REAUTHORIZATION OF HEALTH LEGISLATION, 1982

HEARING

BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES UNITED STATES SENATE

NINETY-SEVENTH CONGRESS

SECOND SESSION

ON

S. 2311

TO REVISE AND EXTEND PROGRAMS RELATING TO BIOMEDICAL RESEARCH, RESEARCH TRAINING, MEDICAL LIBRARY ASSISTANCE, HEALTH INFORMATION AND PROMOTION, AND RESEARCH ETHICS

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REAUTHORIZATION OF HEALTH LEGISLATION, 1982

WEDNESDAY, MARCH 31, 1982

U.S. SENATE,
COMMITTEE ON LABOR AND HUMAN RESOURCES,
Washington, D.C.

The committee met, pursuant to notice, at 11:34 a.m., in room 4232, Dirksen Senate Office Building, Senator Orrin G. Hatch (chairman of the committee) presiding.

Present: Senators Hatch, Hawkins, and Pell.

Senator HAWKINS. I would like to call this hearing to order, please.

I will read into the record Senator Hatch's opening statement:

OPENING STATEMENT OF SENATOR HATCH

The CHAIRMAN. We are holding this Labor and Human Resources Committee hearing to reauthorize some of the most important Federal health legislation. The Biomedical Research, Training, and Medical Library Assistance Act Amendments of 1982, reauthorize the National Cancer Institute, the National Heart, Lung and Blood Institute, the National Library of Medicine Act, the health information and health promotion activities in the Office of the Assistant Secretary of Health and Human Services, and the President's Ethics Commission.

The magnitude and value of the activities encompassed within these programs are staggering. They represent some of our Nation's most successful efforts to improve the health of our citizens.

Since 1930, when the National Institute of Health was officially created, and 1937, when the National Cancer Act established the National Cancer Institute, the Federal Government has assumed a very important role in biomedical research. There has been a tremendous investment in money and energy. This has resulted in the "birth" of multiple institutes which fund a wide variety of health-related research and conduct training programs for scientists at universities across the Nation.

Most critics of our Federal health policy agree this investment has paid off handsomely. The National Institutes of Health are clearly the flagship of research institutes and enjoy a position of unquestioned worldwide leadership. In fact, 76 Nobel Prizes have been awarded to scientists for research funded by NIH programs. The knowledge gained from this research has conquered disease, extended life, and improved the quality of people's lives everywhere on earth.

I support our Government's commitment to support biomedical research. This is a proper and practical role for the public sector. We as elected officials have a duty to closely scrutinize this Federal presence. We are obligated to serve as advocates for our citizens by ensuring that their money and their tax dollars are spent efficiently and properly.

The budget of the NIH, and particularly the Cancer Institute and the Heart, Lung and Blood Institute, has grown by leaps and bounds. It is awesome to recall that in 1965 the NIH budget was $715 million and now approaches $3.8 billion. This grand scale investment requires effective and ongoing congressional oversight. As long as I am chairman of this committee, this will be done.

Today we are meeting to consider legislation which will preserve and continue work of the two largest institutes and the National Medical Library Assistance Act. We also seek to reauthorize the activities of the Office of Disease Prevention and Health Promotion in the Office of the Assistant Secretary of Health and Human Services and the President's Ethics Commission.

The legislation we are considering is a relatively simple reauthorization bill intended as a vote of confidence in the scientists and administrators at NIH. We are proud of their achievements and want them to continue their great work with adequate funds to attract the best and the brightest scientific minds. Indeed, I have proposed in this bill a budget authority for fiscal year 1983 for the NCI and the NHLBI at 6 percent over the fiscal year 1982 budget and believe a similar increased level of overall funding for NIH is essential if we are to maintain our current research effort.

Preparing for these hearings and the oversight hearings of the National Cancer Institute last year has brought many problems to our attention, and some of them are potentially serious. My approach to these problems is not to legislate solutions but to convey the concerns of our citizens to NIH and administration officials, with the full expectation that they will respond with efficient and effective solutions.

Therefore, we hope to highlight some concerns today and will schedule future oversight hearings to insure our citizens obtain the benefits expected from such a great investment. One of the examples of the many concerns I have learned about is the apparently inadequate research effort being devoted to prevention, cure, and treatment of arthritis and related diseases. These diseases afflict more than 30 million Americans, and this magnitude of suffering and disability merits an increased research effort.

I support the intent of Senators Goldwater and Cranston in Senate bill 1939; that is, to facilitate improved research in arthritis. But a legislative restructuring of NIH is not the solution at this time. Instead, we are hopeful the goal of improved arthritis research can be accomplished by officials at NIH recognizing the priority and acting accordingly.

Other problems which merit consideration include: number one, concern about proposed decreases in institution support funded in "indirect costs" or grants and contracts; two, how can we guarantee the young scientists a reliable future in biomedical science and encourage them by giving priority to funding new research grants; three, an apparent increase in fraud and falsification of data

among research scientists, which is frightening; number four, inadequate support for research directed at preventive medicine; and, five, inadequate funding of research equipment and instrumentation which has become so essential to basic researchers.

We are looking forward to hearing testimony from the administration, including the Acting Director of NIH and the Directors of the Institutes being considered today. We invited Dr. Armand Hammer, chairman of the President's Cancer Panel, who has proven to be an effective and energetic leader in this important position. Unfortunately, we learned just yesterday that Dr. Hammer would not be able to join us. We will submit Dr. Hammer's testimony which articulates the success and future needs of the war on cancer.

We have with us today Mr. Paul Rogers, former Congressman from the State of Florida, who served so effectively as chairman of the House Health Subcommittee until his retirement in 1978. He graciously has agreed to come and provide testimony regarding the Cancer Act.

I am very pleased that the dean of the University of Utah College of Medicine has joined with us to provide testimony on behalf of the Association of American Medical Colleges.

Senator HAWKINS. We are going out of order at this time and ask that Mr. Paul Rogers come forward, please. We really appreciate his being here today.

Senator Pell has joined us. Do you have comments at this time, or would you just like us to go forward?

Senator PELL. No, just that we are delighted to see Congressman Rogers, and we want to welcome him.

Mr. ROGERS. Thank you.

STATEMENT OF HON. PAUL ROGERS, FORMER CHAIRMAN OF THE HOUSE SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

Mr. ROGERS. Thank you very much, Madam Chairman. You are very kind to allow me to give my testimony at this time, and I am delighted to see Senator Pell here again in his official position.

It is a pleasure to be before this committee again. I think the last time was some years ago when we were dealing with some regulations Cap Weinberger was about to put out at the time. That is when he was Secretary of HEW. I guess the Congress may be still dealing with Cap, as he has some different regulations.

Senator PELL. In those days he was contracting things; in these days he is expanding. That is the only difference.

Mr. ROGERS. That is right, exactly.

Also, I am delighted that the Senator from my State is presiding. I am very honored that she would be here.

I do appear as a private citizen, however. But I am delighted to be here and to discuss for just a few minutes the legislation to provide continued authority for the Federal biomedical research training and medical library programs. Not to provide significant support for health research is to condemn future generations of Americans to reliance on current medical knowledge. The legislation before the committee would help to assure that this does not

happen by continuing the basic congressional commitment to Federal biomedical research.

The programs included in this legislation deal with several of the most important health concerns of the American people; in particular, the number one and two causes of death in this Nation, heart disease and cancer. Congress recognized the need to emphasize efforts to combat these and other major diseases, and it is gratifying to me to follow the significant progress that has been made in our knowledge of the prevention and treatment of these diseases.

For example, there has been a reduction in the cardiovascular death rate of some 30 percent since 1968, a rather amazing figure. In the sixties, only 10 percent of children with cancer were considered curable. In the 1980's, it is 50 percent and, in some particular cancers, as high as 90 percent.

For the American people now, a cancer diagnosis is no longer an automatic sentence of death. The 1971 amendments to the National Cancer Act represented a quantum leap in our efforts to identify the causes, treatment, and cures of this dread disease. It is interesting to note, I think, Madam Chairman, that this initiative to increase the national commitment to fight cancer came from the Congress and not from the executive branch.

The main thrust of the 1971 law was to increase Federal support, tax dollars for research, cut the redtape for the Institute, and insure a better balance between basic and clinical research, to establish cancer centers for treatment spread around the country quickly, and the opportunity for community physicians to apply the latest knowledge to those who suffer. I know of the Senator's great concern about that particular phase of the cancer effort. I noticed in the paper this morning the announcement again of what was happening, and I think the Assistant Secretary will go into that in his testimony.

Cancer control, in the 1971 amendments, was given greater priority, and certainly prevention was becoming an admitted goal accentuated by increased knowledge of environmental factors that could cause cancer. Indeed, 1971 was a watershed year for the Government's role in cancer research, not only because of the expanded role conferred by the National Cancer Institute, but also, and perhaps more importantly, because of the understanding of cancer research that the American public acquired as a result of the debate regarding the interplay of research and the proper relationship of the NCI and other research institutes.

A host of cancer researchers, many of them recipients of the Nobel Prizes, made the public aware that cancer research would produce no magic bullet, no total cure, but instead the complexities of the disease itself demand a steady and continuous research effort combining both basic and applied research.

As a result of the debate, the Congress and the American public, in my judgment, have a more sophisticated understanding of what Government can and must do to support cancer research. Equally important, I believe the public understands that there are limitations, that the multifaceted aspects of cancer and its causes are such that what must be expected is constant progress and not a dramatic announcement that cancer has been cured overnight.

The role of Government in biomedical research, then, has been principally to bring together the best scientific thought of the times, to support avenues of research that appear most promising, using a peer review mechanism. Also, to provide facilities support and to create an arena for freedom of thought and action for the best minds in our scientific community has certainly been an overall objective.

Madam Chairman, I support and would urge approval by the Congress of continued authorizations for funding of biomedical research in the areas of cancer and heart, lung and blood, and for medical libraries. This committee must make difficult decisions, of course, particularly during the current national economic conditions. There will undoubtedly be legitimate differences of opinion over such matters as overall funding levels that this committee and the Congress must decide upon, appropriate percentages for indirect costs and institutional support, which is most important, and the authority of the National Cancer Institute Director to make direct budgetary submissions to the President, which is of great concern, I am sure, to the American Cancer Society.

This is to be expected that these legitimate differences would be debated here in this forum. However, I am certain, Madam Chairman and members of the committee, that during your committee's deliberations and in conference meetings with the other body, a consensus on the particulars of the legislation will develop which will best serve the interests of the Nation in an effective program of biomedical research and provide hope for those who suffer.

You are very kind to allow me to appear, and I know this committee will make the proper judgments as it deals with the other body.

Senator HAWKINS. Thank you, Congressman. We have a few questions for you.

Mr. ROGERS. Certainly.

Senator HAWKINS. I know that no one in this room need be told your background in interest and expertise in the subject that you speak about today and that you are a current member of the board of directors of the American Cancer Society.

In 1971, you and your colleagues made a judgment that it was necessary to have a concentrated national effort of great magnitude with respect to the cancer program, which you spoke about in your statement. Now, looking back, 10 years later, does that judgment remain valid?

Mr. ROGERS. I think it was a valid judgment and I think it still continues to be a valid judgment because, without question, even though it is not the major cause of death, it is the second, and it is the most dreaded disease.

The American public has strongly wanted the Congress to emphasize programs of research on cancer. My own personal experience has been that cancer touches the lives of almost every family in this Nation. I think the concern for people to have significant support for research is very clear, and the Congress made the right judgment and, I think, will continue to do so.

Senator HAWKINS. Do you think the basic structure of the Cancer Act as it is currently written is sound for the eighties?

Mr. ROGERS. Perhaps I am prejudiced in answering that question, Madam Chairman, but I do think the basic outline of the approach is sound. I think it allows for the scientific community to be supported properly. I think it is designed to make the proper judgments in its relationship with the National Cancer Institute to the President. So I think the basic design of the act is a good one. Every piece of legislation, of course, can be changed as the situation develops; I understand that. But the basic pieces of the legislation, I think, are still sound and will serve the Nation well in the eighties.

Senator HAWKINS. There is a lot of controversy about how much of the National Institutes of Health budget goes for indirect costs; that is, support for universities' overhead, as opposed to direct support for research projects. As you know, we are all concerned today with costs, but we are also concerned that we assure the research capability of our Nation's great research universities.

From your experience, what is the best way to handle this problem?

Mr. ROGERS. Well, I think we had to debate that question, too, and it will be continually debated. I think it is important, as you state in the question, that our institutions must be strongly supported and particularly now when there is a reduction of support and funding from other areas. So certainly research needs to be supported strongly, and I think a proper proportion should go to institutional support and indirect support as well as direct.

Now, there is always that debate, is it going to be simply direct or can some of the funds be used for indirect? I think it is essential to have substantial indirect funding as well.

Senator HAWKINS. Thank you so much, Mr. Rogers.

Mr. ROGERS. Thank you, Madam Chairman, for your courtesy.

Senator HAWKINS. It is a pleasure to see you again.

Mr. ROGERS. Thank you.

Senator HAWKINS. We will look forward to working with you in the future on this subject.

We will excuse you at this time, and I would like to enter in the record Dr. Hammer's statement. He did have a statement. He was unable to be here.

[The prepared statement of Dr. Hammer follows:]

STATEMENT BY DOCTOR ARMAND HAMMER
CHAIRMAN, PRESIDENT'S CANCER PANEL
BEFORE THE
COMMITTEE ON LABOR AND HUMAN RESOURCES
UNITED STATES SENATE
WEDNESDAY, MARCH 31, 1982

MR. CHAIRMAN, MEMBERS OF THE COMMITTEE:

I AM PLEASED TO HAVE THE OPPORTUNITY TO APPEAR BEFORE THIS COMMITTEE TODAY AS IT TAKES UP THE IMPORTANT SUBJECT OF THE LEGISLATION REAUTHORIZING THE NATIONAL CANCER INSTITUTE, THE NATIONAL HEART, LUNG AND BLOOD INSTITUTE, AND THE NATIONAL LIBRARY OF MEDICINE ACT. THESE ARE THREE OF OUR MOST IMPORTANT NATIONAL HEALTH ORGANIZATIONS, BUT I WILL CONFINE MY REMARKS TODAY TO THE NATIONAL CANCER INSTITUTE.

I HAVE NOT HAD THE PLEASURE OF APPEARING BEFORE THIS COMMITTEE PREVIOUSLY. HOWEVER, SINCE MY APPOINTMENT LAST OCTOBER BY PRESIDENT REAGAN TO THE POSITION OF CHAIRMAN OF THE PRESIDENT'S CANCER PANEL, I HAVE STUDIED THE TRANSCRIPTS OF YOUR VARIOUS HEARINGS INVOLVING THE NATIONAL CANCER PROGRAM. I HAVE BEEN MUCH IMPRESSED BY THE DEPTH OF KNOWLEDGE SHOWN BY THE COMMITTEE MEMBERS AND STAFF IN THIS COMPLEX FIELD, AS WELL AS YOUR OBVIOUS DEDICATION TO THE HEALTH AND WELFARE OF THE NATIONAL CANCER PROGRAM AS CARRIED OUT BY THE NATIONAL CANCER INSTITUTE.

I SHARE THAT DEDICATION FOR I HAVE A LONG STANDING DEEP PERSONAL CONCERN ABOUT CANCER. ALTHOUGH I HAVE A MEDICAL DEGREE FROM COLUMBIA UNIVERSITY, I HAVE SELDOM PRACTICED MEDICINE SINCE UNFORSEEN EVENTS THRUST ME FROM FIGHTING A THYPUS EPIDEMIC INTO AN INTERNATIONAL BUSINESS CAREER. I HAVE MAINTAINED A LIFE-LONG INTEREST IN MY ORIGINAL FIELD, THOUGH, AND HAVE TRIED TO KEEP UP WITH THE STATE OF THE ART THROUGH SCIENTIFIC JOURNALS AND OTHER MEANS. IN ADDITION, I HAVE ESTABLISHED THE ANNUAL ARMAND HAMMER CANCER CONFERENCE AND FUND AT THE SALK INSTITUTE IN LA JOLLA , ENDOWED THE JULIUS AND ARMAND HAMMER HEALTH SCIENCES CENTER AT COLUMBIA, AND HAVE PARTICIPATED IN THE CALIFORNIA INSTITUTE FOR CANCER RESEARCH AT UCLA. THUS, I BELIEVE I MAY HAVE DONE MORE TO ASSIST IN MY ORIGINALLY CHOSEN FIELD THAN IF I HAD REMAINED IN MEDICINE. THIS HAS AFFORDED ME A CONSIDERABLE AMOUNT OF SATISFACTION OVER THE YEARS.

BUT MY GREATEST SATISFACTION CAME LAST OCTOBER WHEN I WAS APPOINTED TO THE PANEL. I KNOW YOU ARE ALL FAMILIAR WITH MY TWO DISTINGUISHED COLLEAGUES ON THE PANEL, DR. HAROLD AMOS AND DR. BERNARD FISHER. IT IS A PRIVILEGE TO WORK WITH THEM AS WELL AS WITH DR. DEVITA AND THE MEMBERS OF HIS FINE STAFF AT THE NATIONAL CANCER INSTITUTE.

IN ACCEPTING THE APPOINTMENT, I ASSURED THE PRESIDENT THAT I WOULD DEDICATE MY ENERGY AND RESOURCES TO THE WORK OF THE PANEL TO PROMOTE AND ASSIST THE SUCCESS OF THE NATIONAL CANCER PROGRAM.

AS I LEARN MORE ABOUT THE EXCITING WORK BEING DONE IN CANCER RESEARCH AND THE POSSIBILITIES IT HOLDS FOR THE FUTURE, I AM EVEN MORE DETERMINED TO DEVOTE AS MUCH OF MY TIME AND ENERGY AS POSSIBLE TO AIDING RESEARCHERS AND SCIENTISTS IN THEIR WORK AND HELPING TO ATTRACT OTHER LEADERS IN THE BUSINESS COMMUNITY AND THE PRIVATE SECTOR TO GIVE THEIR SUPPORT TO THIS IMPORTANT FIELD.

THE MAIN CONCERN OF ALL OF US IS TO FIGHT AND ULTIMATELY CONQUER CANCER, THE SECOND LEADING CAUSE OF DEATH IN THE UNITED STATES. IT WILL CLAIM SOME 425,000 LIVES THIS YEAR. IF WE WERE AT WAR, AND THERE WERE SUCH EXTRAORDINARY CASUALTIES ON THE BATTLEFIELD, I AM SURE THE AMERICAN PEOPLE WOULD NOT LONG TOLERATE SUCH LOSSES. I AM CONVINCED THAT THE PUBLIC AND PRIVATE SECTORS CAN WORK TOGETHER AND USE THEIR JOINT RESOURCES TO WIN THE CANCER BATTLE. TO ACCOMPLISH THIS, WE MUST DEVELOP GREATER INVOLVEMENT BY THE PUBLIC AND THE PRIVATE SECTOR IN THE CANCER PROGRAM. WE NEED MORE GRANTS FROM FOUNDATIONS, PHILANTHROPIES AND OTHER CHARITABLE INSTITUTIONS, AS WELL AS INDIVIDUAL CITIZENS. WE MUST CARRY A CLEAR MESSAGE TO ALL AMERICANS TO STIMULATE THEIR SUPPORT AS WELL AS INFORM THEM OF THE ADVANCES THAT HAVE BEEN RECORDED DURING THE PAST DECADE SINCE THE NATIONAL CANCER ACT WAS ENACTED INTO LAW.

THE SCIENTIFIC ACHIEVEMENTS SO FAR ARE TO ME REMARKABLE. IN THE 1960's ONLY 10 PER CENT OF CHILDREN WITH CANCER WERE CONSIDERED "CURABLE." IN THE 1980'S IT IS FIFTY PER CENT. THE NCI FIGURES ON RELATIVE SURVIVAL RATES SHOW AN INCREASE FROM 41 TO 46% FROM 1973 TO 1979.

WE HAVE LEARNED MUCH ABOUT NEW OPPORTUNITIES FOR CANCER PREVENTION. REVOLUTIONARY NEW TECHNOLOGIES HAVE BEEN DEVELOPED THROUGH BASIC RESEARCH, FOR EXAMPLE DNA RECOMBINANT TECHNOLOGY AND WHAT IS TO ME AN ESPECIALLY EXCITING DEVELOPMENT, THE HYBRIDOMA TECHNIQUE.

EARLIER THIS MONTH I SPONSORED A HYBRIDOMA CONFERENCE AT THE SALK INSTITUTE IN LA JOLLA. EXPERTS IN THE FIELD FROM THE UNITED STATES, EUROPE, JAPAN, ISRAEL, THE SOVIET UNION AND THE PEOPLE'S REPUBLIC OF CHINA WERE PRESENT FOR AN INTENSIVE, TWO-DAY SESSION. THE CO-DISCOVERER OF HYBRIDOMA, DR. GEORGES KOHLER, OF THE BASEL INSTITUTE GAVE AN ILLUMINATING TALK. DR. DEVITA WAS ALSO PRESENT AND LATER TOLD ME HE THOUGHT IT WAS EXCELLENT AND REPRESENTED THE CUTTING EDGE OF THE RESEARCH IN THE FIELD. A NUMBER OF OTHER PARTICIPANTS EXPRESSED SIMILAR SENTIMENTS, AND I AM PLEASED TO HAVE BEEN ABLE TO MAKE THE CONFERENCE POSSIBLE. I HOPE TO CONTINUE TO SUPPORT SUCH MEETINGS, FOR WE ALL KNOW THAT SCIENCE RECOGNIZES NO NATIONAL BOUNDARIES AND DEPENDS FOR ITS PROGRESS ON THE WIDEST EXCHANGE OF INFORMATION POSSIBLE.

I HAVE JUST RETURNED FROM BOSTON WHERE THE FIRST MEETING OF THE YEAR OF THE CANCER PANEL WAS HELD. IT WAS ONLY THE SECOND OR THIRD PANEL MEETING HELD OUTSIDE THE CONFINES OF WASHINGTON IN THE LAST DECADE.

IN OUR ATTEMPT TO MAKE THE PANEL A MORE VITAL FORCE IN THE NATIONAL CANCER PROGRAM, DR. AMOS, DR. FISHER AND I AGREED NOT TO LIMIT OURSELVES TO WASHINGTON AS A SETTING FOR MEETINGS. WE WANT TO BE IN TOUCH WITH AS WIDE A SEGMENT OF THE SCIENTIFIC COMMUNITY AS POSSIBLE, SO WE WILL HOLD A SERIES OF MEETINGS IN SEVERAL CITIES OVER THE NEXT 18 MONTHS.

THE BOSTON MEETING WAS HELD AT THE HARVARD SCHOOL OF PUBLIC HEALTH, AND REPRESENTATIVES OF A NUMBER OF CONCERNED INSTITUTIONS WERE INVITED TO MAKE PRESENTATIONS. WE HAD A LIVELY AND STIMULATING SESSION. I BELIEVE ALL WHO WERE THERE AGREE IT WAS WELL WORTH THE EFFORT REQUIRED TO PUT IT TOGETHER. OUR NEXT MEETING WILL BE IN LOS ANGELES IN JUNE, HOSTED BY THE UCLA JONSSON COMPREHENSIVE CANCER CENTER.

IN ALL OF THIS ACTIVITY, I HAVE BECOME INCREASINGLY AWARE OF THE HIGH REGARD IN WHICH THE NCI IS HELD THROUGHOUT THE COUNTRY. I BELIEVE DEEPLY IN THE MANDATE OF THE NATIONAL CANCER PROGRAM AS DESCRIBED IN THE NATIONAL CANCER ACT OF 1971. THE IMPETUS GIVEN TO THE NCI BY THIS ACT HAS WORKED, AND WE HAVE JUST WITNESSED A REMARKABLE DECADE OF DISCOVERY. THE ACCOMPLISHMENTS OF THIS DECADE HAVE BEEN BEAUTIFULLY DESCRIBED IN A PUBLICATION OF THE SAME NAME PREPARED BY THE NATIONAL CANCER ADVISORY BOARD.

THERE HAVE BEEN PROBLEMS, OF COURSE, AS IS TO BE EXPECTED IN A PROGRAM OF THIS SIZE, BUT THE PROGRAM IS WORKING AND WORKING WELL. DR. DEVITA HAS COMPLETED MAJOR MANAGEMENT IMPROVEMENTS WHICH, AS A BUSINESSMAN, I APPLAUD. THE MOST EFFECTIVE MANAGEMENT AND SCIENTIFIC PROGRESS OF NCI DEPEND ON THE AVAILABILITY OF TOOLS PROVIDED BY THE NATIONAL CANCER ACT. I AM GENERALLY SATISFIED THAT THE ACT OF 1971 AS AMENDED IN 1974 AND 1977 PROVIDES THE AUTHORITIES

AND PROVISIONS THE DIRECTOR NEEDS TO MANAGE AND COORDINATE THE NATION'S CANCER EFFORT, BUT I BELIEVE TWO CHANGES PROPOSED BY NCI AND SUPPORTED BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES WOULD BE DESIRABLE. THOSE ARE TO EXTEND FOR THREE YEARS THE APPROPRIATIONS AUTHORIZATION FOR NCI, AND TO EXTEND THE PERIOD OF SUPPORT FOR CANCER CENTER GRANTS FROM THREE TO FIVE YEARS WITH EXTENSION BY THE DIRECTOR, NCI, FOR ADDITIONAL PERIODS OF NOT MORE THAN FIVE YEARS.

MR. CHAIRMAN, THAT COMPLETES MY PRESENTATION. I WILL BE GLAD TO RESPOND TO ANY QUESTIONS THE COMMITTEE MAY HAVE.

Senator HAWKINS. At this juncture, we have made an administrative decision that the committee will stand in recess until after the vote is completed.

[Recess taken.]

Senator PELL. The committee will be in order. At the invitation of Senator Hatch, the chairman, I will open up the hearing. Do each of you have statements that you want to make?

Dr. BRANDT. Actually, I have the only statement that will be read, Senator.

Senator PELL. Well, Senator Hatch will be coming over here and will want to hear you, and I need to leave in a few minutes. Will you permit me to ask you a couple of questions before you read your statement?

Dr. BRANDT. Please.

Senator PELL. This is a subject that particularly concerns Dr. DeVita, and that is the International Cancer Research Data Bank, which came out of a legislative proposal of this committee about 10 years ago. It was my proposal, actually.

Does the present legislation affect the International Cancer Research Data Bank in any way?

Dr. DEVITA. The Research Data Bank will continue.

Senator PELL. It will continue?

Dr. DEVITA. Yes.

Senator PELL. The program, when we started it, was designed to do two things: One, keep track of all the research experiments it could and be able to put the results of that in a bank so that some other university or someone in some other nation might duplicate the same experiment if they knew the experiment and results were available. The other purpose we had was to make sure that a doctor in Oshkosh, in the United States, or in Succotash, in the United States, or in Turin, Italy, or in a little town in Italy, who did not know what the best treatment for particular cancer symptoms would be, could plug a phone into a computer and describe the symptoms, and the data bank would come back with the most up-to-date treatment for those symptoms.

How are you moving in both these directions and how truly international has the data bank become?

Dr. DEVITA. Well, let me answer the last part first. Some 80 countries have access to the International Cancer Research Data Bank computer, so that there is plenty of access to it. The cancer lit, which records several hundred thousand pieces of literature that have been published, and cancer proj, which records some 20,000 ongoing projects that are supported by the Institute, are up and running.

Senator PELL. What are those two names again?

Dr. DEVITA. They are abbreviated names. Cancer lit has an extensive——

Senator PELL. For cancer literature?

Dr. DEVITA. Cancer literature, and cancer proj is the listing of cancer projects that are being supported. There are some 20,000 that are on line, and I use it frequently myself, Senator Pell.

The third part of it is called clin prot, which really is——

Senator PELL. Called what?

Dr. DEVITA. Clin prot, which is an abbreviation for the clinical protocols that are on line. This part is now, at the present time, being modified into a new system we have been referring to as PDQ, patient data query system, which will do exactly what you have just described. The first phase was to get all the protocols on the computer, which we have done and had for a number of years. The second phase is now to make it a very interactive system so that a doctor can get into the system and find anything he wants. If the patient has breast cancer, he can find where any kind of research is going on with that particular disease near their facility by plugging in the area code, which will then print out a list of who is doing what in that area.

Then the third phase will be a very interactive system that will allow anybody with a home computer to plug into the system, patients and families and so forth.

Senator PELL. I visited the International Cancer Center at Lyon some time ago and talked to Dr. DeFrinne who, I am sure you know, is the president of the League Against Cancer in Geneva.

Dr. DEVITA. Yes, indeed.

Senator PELL. He was not familiar with the Cancer Data Research Bank.

I also talked to one of the chief surgeons at Memorial Hospital in New York. He was not familiar with it. I am wondering who knows about this bank and the material that is available. I see people making proposals along these lines all the time. If it is already in being, as I think it is through my legislation, why is it that information about this is not well known?

In my own State of Rhode Island, the hospitals are not aware of it.

Dr. DEVITA. There are many people who are aware of it, Senator, but not everybody is aware of it. It is like most things: One has to develop the user pool for it. I think, in looking at the three groups I have mentioned, the one that was the least useful for the average physician was the clin prot. It was useful for us because we were able to have on line a list of all our protocols. But it was not useful for the average doctor to get a detailed description of a protocol to treat a cancer patient. What the average doctor really wanted was to know who is doing what in general terms with their disease.

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This new modification, we think, will be very popular and will be widely used.

The Europeans have been more interested in another part of the internatioanal cancer program, which is, abbreviated—I am sorry for all the abbreviations—ICRETT, which is basically a system——

Senator PELL. What does ICRETT mean?

Dr. DEVITA. I really cannot even get all the initials straight myself, but I will describe to you what it is.

Senator PELL. Maybe, for the record, you could submit what the name is.

Dr. DEVITA. Yes. It is a pool of money that was used for exchanging scientists between countries for short periods of time to learn the techniques that one scientist was using in another country; in other words, to support training for periods of a month or two.

[The information referred to follows:]

ICRETT refers to the International Cancer Research Technology Transfer Program.

Senator PELL. My recollection is that there are five centers for the data bank? Isn't that correct?

Dr. DEVITA. That is right.

Senator PELL. Four in America and one in—is it France or Germany?

Dr. DEVITA. I think it is in Switzerland.

Senator PELL. Switzerland. One in Switzerland and four in America.

Dr. DEVITA. That is right.

Senator PELL. Do you remember where those centers are?

Dr. DEVITA. No, I do not offhand.

Senator PELL. Maybe you could submit those for the record.

Dr. DEVITA. Yes.

[The information referred to follows:]

The International Union Against Cancer (UICC) is located in Geneva, Switzerland. The Current Cancer Research Projects Analysis Center (CCRESPAC) has, until recently, been located in Washington, D.C. This project is being recompeted; therefore, its future site is unknown.

There are three Cancer Information Dissemination and Analysis Centers (CIDC) in the U.S.A. Two are in Philadelphia, Pennsylvania, and one is in Houston, Texas.

Senator PELL. Is any use of our bank made by the countries behind the Iron Curtain, by the Soviet Union?

Dr. DEVITA. I don't believe so, no.

Senator PELL. Wouldn't it be a good idea to widen the exchange to China?

Dr. DEVITA. We are willing to widen it as broad as anybody wants to widen it, Senator. I am not 100 percent sure that we do not, but I don't believe we do have any——

Senator PELL. Is any use of it made by Western Europe?

Dr. DEVITA. Oh, yes, a good deal.

Senator PELL. Substantial. How about China?

Dr. DEVITA. I don't believe so at the present time.

Senator PELL. How about Latin America?

Dr. DEVITA. Yes, some. We have an international agreement through PAHO with a number of South American countries, and they do use it.

Senator PELL. How many inquiries a year, roughly, do you receive domestically and from outside the United States?

Dr. DEVITA. I just do not have those data at my fingertips, Senator, but actually, quite a few. We recently had a user survey of the various components, and the cancer lit and clin proj are queried often, but the clin prot is queried about 20 hours a month, which is not as high as we would like to have it.

Senator PELL. When you say many, do you mean in the tens, the hundreds, the thousands, or the tens of thousands?

Dr. DEVITA. Cancer lit turns out to be in the tens of thousands of inquiries, I believe. I am guessing now; I was not prepared to answer these questions at this particular time.

Senator PELL. I did not mean to spring this on you. Because this was my legislation, I am particularly interested in it.

Dr. DEVITA. The user survey was done, and I saw it about 6 months ago, and I do have the exact figures, and I will be happy to supply them for the record for you.

[The information referred to follows:]

Utilization of the International Cancer Research Data Bank (ICRDB)

The primary purpose of the International Cancer Research Data Bank (ICRDB) program is to facilitate the transfer and exchange of cancer research information generated worldwide, by systematically and actively collecting, analyzing, organizing, and disseminating this information in a targeted fashion to many specific user groups. This program provides easy access to published cancer research results and ongoing research project information through both current awareness and archival mechanisms. This information provides essential background data needed for design of effective new and ongoing research projects, reduces unproductive experimentation and duplication of effort, and enhances the return on the investment in cancer research.

A vital part of the ICRDB is the computer data base system-CANCERLINE. CANCERLINE is composed of CANCERLIT, CANCERPROJ, AND CLINPROT. CANCERLIT is a bibliographic data base on the cancer literature derived from 3,000 serials, books, and reports, and material selected from professional meeting abstracts. It contains more than 250,000 references dealing with various aspects of cancer. CANCERPROJ contains descriptions of ongoing cancer research projects in many countries. CANCERPROJ has nine to ten thousand new or modified research projects entered per year, and has a total of approximately 20,000 items on-line, covering the most recent three-year period. CLINPROT is an on-line version of the National Cancer Institute's Compliation of Clinical Protocol Summaries, a hard-copy publication. This data base serves as a summary of the approximately 2,900 experimental protocols for cancer treatment now underway.

The ICRDB also collects, analyzes and disseminates three types of data worldwide via on-line data bases and special targeted publications. They include:

* Abstracts of the published literature: The classical types of literature such as journals, books, reports, and other monographs are supplemented by announcements of the recent results presented at scientific conferences and symposia.
  - 300,000 abstracts are readily available for searching through the on-line data base CANCERLIT.
  - 40,000 new abstracts are entered into the data base each year and are actively disseminated directly to cancer researchers in a highly targeted and selective fashion through two series of publications -- CANCERGRAMS and ONCOLOGY OVERVIEWs.
* Descriptions of current research projects from 83 countries around the world:
  - 20,000 descriptions of current research projects are available through on-line searching of CANCERPROJ and are actively disseminated directly to researchers through publications.
* Summaries of current cancer therapy protocols
  - Some 3,000 summaries of these experimental protocols are available through CLINPROT. Summaries of active protocols are published in an annual compilation which is mailed to clinical oncologists.

Virtually all users of the products and services of the ICRDB program are engaged in cancer research or treatment of cancer patients. According to the National Library of Medicine estimates, in 1981 53,187 on-line and off-line searches were conducted on the CANCERLINE data bases.

These searches represent both domestic and international data requests and resulted in the off-line printing of 374,540 pages containing 823,488 abstracts. The National Cancer Institute estimates that at least 40 percent of all CANCERLINE searches are related to therapy and treatment issues.

The ICRDB is used extensively in the United States and in other countries. Because of the variety of ways in which CANCERLINE is utilized by other countries, it is difficult to provide overall international utilization figures. Some countries choose to obtain and mount IDRDB data tapes to provide information to those engaged in cancer research and treatment; therefore, it is impossible to know the precise amount of searching and printing that may occur.

Recent ICRDB worldwide distribution of publications is as follows:

- CANCERGRAMS: 24,000 issues per month covering 66 topic areas
- ONCOLOGY OVERVIEWS: 9,000 issues per year, covering 15 topic areas
- SPECIAL LISTINGS: 55,000 issues per two-year cycle, covering 55 topic areas.
- COMPILATION OF EXPERIMENTAL CANCER THERAPY PROTOCOL SUMMARIES: 7,500 issues per year.

Senator PELL. The thing that got me a little burned up was that I found several doctors who are very competent in the field of cancer at leading hospitals in both New York and Rhode Island utterly unaware of this program.

Dr. DEVITA. Yes, indeed. I know that is a constant problem with these kinds of programs in terms of making people aware of them. Now, we also prepare cancer grams. Really, it is essentially these five centers that you referred to that look at what is available and take an area of science that seems to be most current and put it together in a cancer gram, and we distribute these very widely to individuals around the country, trying to make them aware of the fact that this program is there.

Senator PELL. Did you see the story on page 2 of the Washington Post this morning?

Dr. DEVITA. Yes, indeed.

Senator PELL. Does that refer to the International Cancer Research Data Bank?

Dr. DEVITA. There was a small mention of the system I just described to you, the one we refer to as patient data query system [PDQ], in that because they would be linked to it.

Senator PELL. Could you submit for the record, for the last year, or for any calendar year you wish, the number of inquiries that have been made for research and the number of those who in-

quired as far as the modality of treatment goes, divided according for whether the inquiries were domestic or came from outside the United States?

Dr. DEVITA. Certainly.

Senator PELL. If you could do that, I would appreciate it.

How large an operation is the International Research Data Bank?

Dr. DEVITA. It has about 15 people that run it, and it is housed in about 2,500 square feet.

Senator PELL. And is the current budget adequate for its purposes?

Dr. DEVITA. Yes, indeed.

Senator PELL. And what is that budget?

Dr. DEVITA. It is approximately $7 million for the entire International Cancer Research Data Bank and our international activities on the bilateral agreements.

Senator PELL. I would like to break that down between international activities and the International Cancer Research Data Bank.

Dr. DEVITA. I think it is $685,000 for our bilateral agreements, and all the remainder is the International Cancer Research Data Bank.

Senator PELL. Thank you. And what about the proposed 1983 budget? Is that adequate?

Dr. DEVITA. It is about the same. There was a slight reduction between 1980 and 1981 because we reduced some of the programs in size.

Senator PELL. And how do your activities now differ from those of 5 years ago when I made my last inquiry on it? At that point, it was theoretically building up. They did not have a full quiver of arrows. Presumably, by now, you could describe any symptom you wanted to, any kind of cancer, no matter how remote, and there would be an answer.

Dr. DEVITA. Well, the PDQ system will do that. The systems that were set up over the past 10 years were not designed to do that, specifically, but the new system that we are setting up will do that. The first phase was really collecting all the literature and getting it on line and setting up the hardware and software for doing this, which took them a good deal of time.

Senator PELL. Do you have any recommendations to me as to how we from the legislative side could strengthen the International Cancer Research Data Bank and make sure that the information that you have is better disseminated amongst the general community?

Dr. DEVITA. Well, I think this kind of public mention of it is worthwhile, Senator. I think that we really do try our best, through dissemination of information in our public affairs area, to make people aware of these kinds of programs. I am not sure we will ever have every doctor aware of these kinds of systems unless they have a particular interest in the disease. Many doctors are not that concerned with cancer as their primary interest.

Senator PELL. My understanding is that, in the last few years, participation by scientists working in undeveloped countries, has been deemphasized.

Dr. DEVITA. Yes.

Senator PELL. Is that correct?

Dr. DEVITA. Well, there was one program that was based in England that was to provide access to the African Continent which has not been funded.

Senator PELL. Now, is the PDQ that you were referring to, part of the International Cancer Research Data Bank?

Dr. DEVITA. That is a modification of the current clin protocol phase of the International Cancer Research Data Bank, which will be done using the same system but changing it to do what you just described; that is, allowing it to be interactive with a patient or a physician.

Senator PELL. And will the same man who is in charge of the bank be in charge of PDQ?

Dr. DEVITA. Yes. It is about $22 an hour, but patients or doctors don't query the system for more than 5 minutes or so at a time so that it is actually considerably cheaper.

Senator PELL. Would you be kind enough to submit at some point a table of organization that can explain this? I am sure you can do it simply so that one can understand it.

Dr. DEVITA. I would be glad to.

[The information referred to follows:]

ORGANIZATIONAL LOCUS OF THE NATIONAL CANCER INSTITUTE PROTOCOL DATA QUERY SYSTEM (PDQ)

The pilot version of the PDQ system is in its final developmental stage. Operations are expected to begin during the fall of 1982. The development of this system had been coordinated by the NCI Assistant Director who is a part of the NCI Office of the Director. To ensure Institute coordination, a PDQ Task Force was formed that is representative of the following NCI offices and divisions: Office of International Affairs; Office of Cancer Communications; Division of Resources, Centers, and Community Activities; Division of Cancer Treatment; Division of Cancer Cause and Prevention; Office of Program Planning and Analysis; and the Office of the Director. In addition, a representative from the National Library of Medicine has served on this task force.

The utilization of a PDQ task force has allowed for maximum input into the development of this new system and has promoted Institute-wide cooperation. The International Cancer Research Data Bank (ICRDB) program is responsible for implementing the pilot version of PDQ using current ICRDB contractors. The permanent locus for the operation of the PDQ will be determined once the system is fully operational.

Senator PELL. And we look forward to following up on this because it is disappointing, to find that the head of the International Cancer Union has never heard of it, and that the principal cancer hospitals in New York have never heard of it. There is something wrong here, and I would like to get to the bottom of it. I don't think the explanation you have given so far has really given me the answer to that question.

Dr. DEVITA. Well, in part, I think it is really—there is an explanation. If you ask a person who is working in the laboratory, they may use the cancer lit phase of it, but they wouldn't even know the clin prot phase existed because they have no need to.

Senator PELL. Why wouldn't the cancer journals, the AMA journals, and the journals that the physicians read have some mention of this so that doctors working in this field, not necessarily in Succotash but in New York, would be aware of it?

Dr. DEVITA. I think they would. There is a very important reason here, Senator. One is that the way clin prot, the listing of our very complicated protocols, was set up, it is my own personal

feeling that this information is not useful and potentially hazardous to untrained people who are not trained as cancer physicians to use it, and that has not been widely disseminated nor widely advertised, and it is the one that is least used. That is the one we are modifying to make a system along the lines you just described, one that is actually providing the kind of information that you as a patient or a doctor might want immediately with a patient in his office.

Now, the one thing that happened, I believe, that makes that possible now is the availability of home computers. Every doctor's office has a computer system in it now, and every other person seems to be having access to home computers, so we are very excited about the potential now because of the availability of home computers that was not there 5 years ago. It makes a big difference.

Senator PELL. Good. Well, we will do all that we can—at least I will—to encourage you in this. I look forward to visiting the installation at some point.

Dr. DEVITA. Thank you very much.

Senator PELL. Now, on a slightly different subject, the current bill eliminates the authorization for the two sports medicine programs. This concern would be addressed to Dr. Brandt. I realize that these have not been funded in the past, but they have been objectives. Could you tell me what the reason was for wiping them out.

Dr. BRANDT. The bill before you—I presume you are talking about Senator Hatch's bill, specifically.

Senator PELL. Pardon?

Dr. BRANDT. You are talking about Senator Hatch's bill?

Senator PELL. Yes.

Dr. BRANDT. Well, quite frankly, Senator Pell, we have not yet finished our analysis of that bill. We are going to submit legislative language. I am not sure yet precisely what we will do with the two sports programs that you are talking about.

We have, however, strengthened, as you know, the President's Council for 1983.

Senator PELL. How have you strengthened it?

Dr. BRANDT. We have kept its budgetary level up as one of the items in the Public Health Service budget.

Senator PELL. Do you mean it has been increased or it is being level funded?

Dr. BRANDT. It would be level funded.

Senator PELL. But that is not necessarily increasing support, particularly with inflation.

Dr. BRANDT. When you compare it to certain other activities, it is.

Senator PELL. That I realize. And I think that sports medicine plays a role in preventative medicine.

Dr. BRANDT. Yes, sir.

Senator PELL. Good.

Thank you very much indeed, Dr. Brandt, Dr. DeVita. I look forward to being in touch with you on the International Cancer Research Data Bank. Good luck to you.

Dr. BRANDT. Thank you, sir.

Senator PELL. I express my thanks to Senator Hatch for letting me ask my questions. I appreciate it very much, indeed.

The CHAIRMAN. You bet.

We are sorry for all of the rigmarole this morning, but, frankly, I cannot believe all the conflicts we have, and I know that you are used to that, too, Dr. Brandt. But you have a statement. I don't even think you have had a chance to give it yet, have you?

Dr. BRANDT. That is correct. I have not given it.

The CHAIRMAN. Why don't we give you that opportunity?

Dr. BRANDT. All right, sir.

STATEMENTS OF DR. EDWARD N. BRANDT, ASSISTANT SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY THOMAS E. MALONE, ACTING DIRECTOR, NATIONAL INSTITUTES OF HEALTH; DR. VINCENT DeVITA, DIRECTOR, NATIONAL CANCER INSTITUTE; DR. PETER FROMMER, ACTING DIRECTOR, NATIONAL HEART, LUNG AND BLOOD INSTITUTE; AND DR. MARTIN CUMMINGS, DIRECTOR, NATIONAL LIBRARY OF MEDICINE, A PANEL

Dr. BRANDT. Mr. Chairman, I appreciate the opportunity to testify in support of the reauthorization of three vital components of the Nation's effort to promote and maintain health of Americans, namely, the National Heart, Lung and Blood Institute, the National Cancer Institute, and the medical library assistance program of the National Library of Medicine.

Biomedical discoveries to provide the means for improved methods of preventing, detecting, diagnosing, and treating diseases, and the NIH is at the forefront of our efforts and of our Nation's efforts.

The NHLBI and the NCI are extending the frontiers of our knowledge about the two major killers and disablers of our people today. By expanding our biomedical understanding of these maladies, we are moving closer to their ultimate prevention.

The NLM's medical library assistance program represents another important aspect of the mission of the NIH: The timely dissemination of the knowledge secured by our research. The National Library of Medicine is much more than a storehouse of biomedical information. It is the heart of a national—indeed, worldwide—network that offers to researchers and medical practitioners the information they need to provide treatment and save lives.

We are proposing a 5-year reauthorization of the two institutes and the medical library assistance program at the President's requested budget level for fiscal year 1983, and for "such sums as necessary" for fiscal years 1984 through 1987. We do view reauthorization not only as a vote of confidence for the work of these three organizations and for the NIH as a whole, but also as crucial to the maintenance of our preeminent position in developing an understanding of basic, applied, and clinical research processes.

I think that the two institutes and the library program that were discussed today illustrate the excellence in research and information services that has been a hallmark of the NIH. That standard of excellence is possible because of the confidence expressed over the years by this committee and the Congress in the NIH.

The knowledge of basic molecular life processes and the sophisticated technology now in hand will move us, I am sure, into a new age of better health care and well-being for all.

Now, as you know, Mr. Chairman, we are in fact following research both in heart, lung and blood disease and in the National Cancer Institute which is helpful in extending the lives of American people, but I think, in the interest of time, that I will let the specifics of that be entered in the record, and I will not now read that.

However, I do think it is important to point out that the third component that requires reauthorization is the Medical Library Assistance Act program within the National Library of Medicine. This act offers assistance for library resources, research in biomedical communications, training, biomedical publications, and regional medical libraries.

Programs under this act support activities that improve the dissemination of health information, provide direct assistance to maintain a cooperative regional medical library network, and strengthen that network indirectly by improving the resources and services of component libraries. The reaction of the medical community to the efficiency and effectiveness of these services has been quite positive. The assistance provided represents an investment in the transfer of medical information from the laboratory to the bedside, and we are, as I pointed out, requesting a 5-year reauthorization.

In conclusion, Mr. Chairman, continued biomedical research effects of the Cancer and Heart, Lung and Blood Institutes and rapid dissemination of research findings through the National Library of Medicine will make important contributions to better health for all in the immediate future and over the long range. Their work will lead to payoffs in prevention of disease and disability and, not incidentally, to controlling the impact of disease on society.

The Department believes that extension of these programs for 5 years will promote effective planning, continuity of effort, and results. We appreciate the committee's interest in biomedical research, and we believe we are in agreement on this issue. Many of the proposals contained in your bill speak to this interest, Mr. Chairman. However, we have not had sufficient opportunity to review your bill in detail, and we will be happy to work with your committee to develop appropriate legislative language.

Thank you for this opportunity to discuss the importance of these efforts. The Director of each of these programs has a statement that we will enter for the record. Now we and the Acting Director of the NIH, Dr. Tom Malone, will be pleased to answer any questions that you may have.

[The statements referred to follow:]

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

FOR RELEASE ONLY UPON DELIVERY

STATEMENT

BY

EDWARD N. BRANDT, JR., M.D.
ASSISTANT SECRETARY FOR HEALTH
DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE

THE

SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES

MARCH 31, 1982

Mr. Chairman and Members of the Committee:

I appreciate the opportunity to testify in support of the reauthorization of three vital components of the Nation's effort to promote and maintain the health of Americans - the National Heart, Lung, and Blood Institute (NHLBI), the National Cancer Institute (NCI), and the Medical Library Assistance Program of the National Library of Medicine (NLM).

Our biggest budget priority in 1983 is to maintain a strong Federal commitment to biomedical and behavioral research. Biomedical discoveries provide the means for improved methods of preventing, detecting, diagnosing, and treating diseases, and the National Institutes of Health (NIH) is at the forefront of our efforts.

The NHLBI and the NCI are extending the frontiers of our knowledge about the two major killers and disablers of our people today. By expanding our biomedical understanding of these maladies, we are moving closer to their ultimate prevention.

The NLM's Medical Library Assistance Program represents another important aspect of the mission of the NIH -- the timely dissemination of the knowledge secured by our research arms. The NLM is much more than a storehouse of biomedical information; it is the heart of a national (and worldwide) network that offers to researchers and medical practitioners the information they need to provide treatment and save lives.

The Department is proposing a five-year reauthorization of the two institutes and the Medical Library Assistance Program at the President's budget level for FY 1983, and for "such sums as necessary" for fiscal years 1984 through 1987. We view reauthorization not only as a vote of confidence for their work and for the NIH as a whole, but also as crucial to the maintenance of our preeminent position in developing an understanding of basic, applied, and clinical research processes in the biomedical sciences.

NIH

As I mentioned earlier, the two Institutes and the Library Program illustrate the excellence in research and information services that is a hallmark of the work of the NIH. That standard of excellence is possible because of the confidence in NIH expressed over the years by this Committee and the Congress through support of basic biomedical research. Thanks to that backing, the United States is the world leader in the health sciences. At the core of our unprecedented national research capacity is the NIH, which, on behalf of the people, supports and focuses research and knowledge for better health care.

The flood of basic discoveries in biochemistry, physiology, and medicine in recent years offer an historic opportunity to attack and overcome disease and disability. The knowledge of basic molecular life processes, and the sophisticated technology now in hand, will move us, I am confident, into a new age of better health care and well-being for all. To support that confidence, I would like to offer some highlights of the achievements and potential of the three components of the NIH under consideration today.

NHLBI

The NHLBI is pursuing research that will improve the health of Americans with respect to heart, lung, and blood diseases.

A substantial decline in the cardiovascular death rate -- 30 percent since 1968 -- is but one sign of that success. At the same time, it must be recognized that cardiovascular disease is still the cause of over half of the deaths in the United States, and that deaths from chronic obstructive pulmonary disease are rising. These realities show that much remains to be done and demonstrate the continued need for the programs of the NHLBI.

During the two years since authorization of the Institute was last considered, substantial advances have occurred in the three major areas of basic and applied research, clinical trials, and prevention activities. Fundamental and applied research on biological and disease processes have increased our understanding in such areas as arteriosclerosis, hypertension, cystic fibrosis, and Cooley's anemia. Large-scale clinical trials have validated certain approaches before their inroduction into clinical practice. The benefits of treating even so-called "mild" hypertension; the saving of lives through chronic beta-blocker treatment after heart attack; the benefits of continuous, rather than intermittent oxygen therapy in those with advanced chronic obstructive pulmonary disease; the reduction by one-third of neonatal respiratory distress syndrome through the use of the drug dexamethasone in high-risk preganancies near term; and and the effectiveness of a vaccine protective against hepatitis B virus, are all examples of knowledge validation through the conduct of clinical trials.

Also, prevention activities are in place and growing. For example, the National High Blood Pressure Education Program, has been successful in promoting the adoption of proven modalities to control hypertension through health care providers, industry, consumers, minority groups, and other Federal agencies. This has resulted in a marked decline in cardiovascular deaths, particularly those from stroke.

The Administration believes that the NHLBI is fulfilling its mandate effectively under authorities of present legislation. We therefore request that existing authorities be extended for five years, with an authorization level of $36 million for cardiovascular, lung, and blood disease prevention and control programs, and $515.8 million for other NHLBI activities, for fiscal year 1983, with "such sums as necessary" for fiscal years 1984 through 1987. Authorization for NHBLI training programs appears elsewhere in the PHS Act.

NCI

The National Cancer Act of 1971, and its amendments, expanded and intensified the cancer research and control effort in this country. Those actions already are showing results in better cancer care, an increased survival rate which means that an additional 320,000 cancer patients diagnosed in the 1970's are potentially curable, and a drop in cancer death rates for Americans under age 45 and for some common cancers at all ages.

Many recent important developments in basic biology can be attributed to the increased emphasis on cancer research that took place in the 1970's. These developments include the revolutionary techniques of gene cloning with recombinant DNA technology and the production of pure (monoclonal) antibodies with hybridoma technology. Other developments are

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epidemiologic and laboratory studies indicating that various manipulations of dietary constituents may have a role in arresting the late stages of cancer causation.

The National Cancer Act contributed to these advances in several ways:

o Manpower Training. Manpower needed for both research and patient care has increased. In one area alone -- clinically training physicians to specialize in cancer -- the act has had major impact. In the late 1960's, the United States had less than 100 oncologists; by 1980, more than 1,800 physicians were board certified in oncology. Many of these specialists are in private practice, providing medical care to cancer patients and have helped upgrade the level of cancer care at the community level.

o Cancer Centers. These organizations greatly enhance the national capability for cancer research and also serve as important resources to communities for conducting clinical trials and for information dissemination.

o Cancer Control. The legislative authorities, the clinical cooperative groups, the centers, the cadre of cancer specialists at the community level, combined with the knowledge gleaned from research during the 1970's, provide the tools to undertake a new

direction in cancer control. As part of this effort, NCI is beginning in fiscal year 1983:

-- Community Clinical Oncology Progams to bring the latest technology in cancer treatment by involving community physicians and their patients.

-- Cancer Control Research Units that will evaluate the impact of NCI's cancer control programs in defined populations and areas.

-- Applied prevention programs that will attempt to test the value of chemopreventive agents. These are substances such as Vitamin A and its precursors, Vitamins C and E, and trace minerals and antioxidants that appear to interfere with the late stages of carcinogenesis.

Many of these gains can be attributed to specific provisions of the National Cancer Act, and funds that have been authorized under the Act and its amendments over the past decade. The Act provided the Director of the National Cancer Institute the flexibility and authority to carry out its provisions, while maintaining excellent and productive working relationships with the NIH. Maintenance of these authorities is essential to continuing and building on the momentum of the National Cancer Program.

The legislative authorities for the Cancer Program have been instrumental in its success, but good management has been necessary also. Since 1980, NCI has been exmaining its organization and management to improve its overall functioning. Management initiatives in this area include:

-- Clarification and expansion of advisory bodies. For example, all proposed contract projects now receive a concept review from Boards of Scientific Counselors;

-- Establishment of a budget formulation and decision-making process;

-- Contract cost benefit analysis and fund reallocation to more promising activities;

-- major reviews in NCI contracting processes and reviews of space utilization and staffing.

Finally, Mr. Chairman, I know that members of this Committee need no reminder that cancer is the disease that Americans fear most, the disease they most want controlled. Legislation enacted over the past decade has made it possible to develop a program that has made numerous advances, many of them already benefitting people, and promises even more progress in the next decade. Because of this demonstrated soundness, the Administration recommends that

the legislation be continued and that the appropriations authorization for the NCI be extended for five years. We are proposing authorization levels of $55,065,000 for cancer prevention and control programs, and $878,319,000 for other NCI activities, for fiscal year 1983, and "such sums as necessary" for fiscal years 1984 through 1987. Authorization for NCI training appears elesewhere in the Public Health Service Act. We are also requesting that the period of support for cancer centers be extended from three to five years and the option of the NCI Director to renew such grants be extended for an additional five-year period rather than three years, after review by an appropriate scientific group. In the interest of increased management efficiency, we are proposing to repeal the requirement that the NCI Director, submit an annual budget estimate, without change by the NIH Director, or the Secretary, directly to the President for review and transmittal to the Congress.

NLM

The third component of NIH that requires reauthorization is the Medical Library Assistance Act program within the NLM.

This Act, passed in 1965, and since extended, offers assistance for library resources, research in biomedical communications, training, biomedical publications, and Regional Medical Libraries.

Mr. Chairman, we recognize that scientific progress, medical education, and health care delivery are related to our ability to store, retrieve, and disseminate appropriate information in a timely fashion. Programs under the Medical Library Assistance Act support activities that improve dissemination of health information, provide direct assistance to maintain a cooperative Regional Medical Library Network, and strengthen the Network indirectly by improving the resources and services of component libraries in the network. For example, the Computers-in-Medicine Program supports investigations of new applications of computer technology in health care settings, of decision-making processes in health practice, and of new ways of assisting health professionals to draw upon health knowledge and research results in the evaluation and management of health and disease.

As a result of this investment over the years, the Nation's health professionals, even those in small rural towns, can now search the world's biomedical literature, identify the documents they need, and have them delivered as easily as their colleagues in major metropolitan areas. The reaction of the medical community to the efficiency and effectiveness of the these services has been extremely positive.

Health science libraries, as they attempt to cope with the rapidly expanding body of scientific literature, continue to need assistance in collecting information, training competent staff to organize it, applying new methodologies to retrieve it, and maintaining an efficient network through which to share it. The assistance provided by these programs represents an investment in the transfer of medical information from the laboratory to the bedside.

Accordingly, the Administration is requesting a five-year reauthorization, at a level of $7.5 million for fiscal year 1983, and "such sums as necessary" for fiscal years 1984 through 1987, to provide for this program.

CONCLUSION

Mr. Chairman, continued biomedical research efforts of the Cancer and Heart, Lung, and Blood Institutes and rapid dissemination of research findings through the National Library of Medicine will make important contributions to better health for all in the immediate future and over the long range. Their work will lead to payoffs in prevention of disease and disability and, not incidentally, to controlling the impact of disease on society. The Department believes that extension of these programs for five years will promote effective planning, continuity of effort, and results.

we appreciate the Committee's interest in biomedical research, and we believe we are essentially in agreement on this issue. Many of the proposals contained in your bill speak to this interest, Mr. Chairman. However, we have not had sufficient opportunity to review your bill in detail. We will be happy to work with your

Committee to develop appropriate legislation to continue these important programs of the NIH. To this end, we will submit legislative language to your Committee.

Thank you for this opportunity to discuss the importance of these particular efforts. The Director of each of these programs has a Statement for the Record. We will be pleased to answer any questions you may have.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20205

STATEMENT FOR THE RECORD

BY

VINCENT T. DEVITA, JR., M.D.

DIRECTOR, NATIONAL CANCER INSTITUTE

NATIONAL INSTITUTES OF HEALTH

BETHESDA, MARYLAND 20205

BEFORE THE

SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES

MARCH 31, 1982

Mr. Chairman and Members of the Committee:

I am pleased to provide this Committee with information related to the reauthorization of the National Cancer Institute and to highlight the progress made possible by the National Cancer Act of 1971 and its amendments.

That Act now is 10 years old, and all of us who are devoting our work to solving the cancer problem believe that the legislation has had great beneficial impact. The Act expanded and intensified the cancer research and control effort in this country. It provided managerial authorities to effect a degree of coordination of international, government and private anticancer efforts not before seen.

Those associated with the 1971 legislation knew that progress, if it were to come, would be by steady, small increments. Good ideas cannot be bought. But, putting good scientists to work can lead to unexpected discoveries that, in turn, lead to new ideas. This is exactly what happened in the Cancer Program. The biologic revolution we are now witnessing is an example of this process.

Provisions in the cancer legislation allowed the United States to increase substantially the amount of cancer research, to train a new cadre of cancer scientists and physicians, to foster the establishment of cancer centers, and to implement cancer control activities. These actions are already showing results in terms of better cancer care, increasing survival of cancer patients, and decreasing the overall cancer death rates for Americans under age 45, and decreasing some cancer death rates regardless of age. These actions also have brought us to the threshold of being able to prevent cancer on a wide scale.

I believe it is safe to say that in the past 10 years there has been:

- No other chronic disease where greater progress in treatment was made than the more than 100 we collectively call cancer;
- No area of research where a greater understanding of mechanisms of basic biology has occurred than in those diseases we call cancer, and;
- No field of medicine with greater promise for prevention than the one concerned with the diseases known as cancer.

We recently collected the first five-year survival data from our Surveillance, Epidemiology and End Results (SEER) program. This program was set up in response to one of the provisions of the 1971 Act. SEER registries continuously monitor incidence and survival of a 10 percent sample of the population to define the magnitude of the cancer problem within the United States. SEER statistics now show that the relative five-year survival rate for all patients diagnosed with cancer from 1973 to 1979 has risen to 45 percent. For most cancers, the relative survival rate is a reliable indicator of improvements in the management and curability of cancer in general. An earlier NCI study--conducted before SEER was established--showed that patients diagnosed between 1967 and 1973 had a relative survival rate of 40 percent. The increase to 45 percent is an increase in the relative survival rate of 12.5 percent. In human terms, this means that an additional 320,000 patients diagnosed in the 1970s are potentially curable.

Mr. Chairman, let me give you some specific information about how the legislation contributed to these advances: The 1971 Act enabled universities and medical schools to expand their training programs, thus increasing the manpower to tackle the cancer problem. As one example, the country was seeded with a cadre of physician specialists in oncology,

completely changing the potential for how cancer patients are treated. In the late 1960s, there were less than 100 medical oncologists in the entire United States. By 1980 there were more than 1,800 physicians board-certified in this specialty. Likewise, in 1968 there were only 77 physicians who practiced radiation therapy full-time. By 1980 there were more than 1,400 full-time radiation therapists. Many of these specialists are in private practice providing medical care to cancer patients in community hospitals throughout the United States.

The National Cancer Act had another major impact on cancer research and cancer care. It provided the resources to expand the number of comprehensive cancer centers in the United States from 3 in 1971 to 20 today. The NCI supports an additional 24 specialized clinical cancer centers and another 17 research centers. These centers greatly enhance this Nation's capability for cancer research. But they do more. These centers--located throughout the country--have firm regional footings. They serve as important resources to local communities for conducting clinical trials and for disseminating new information. They also form a foundation for a new concept of cancer control.

The concept of cancer control envisioned in the 1971 Cancer Act was a noble one, and in some respects was ahead of its time. But in the early 1970s we lacked some of the important resources needed for technology transfer. Now, with the previously established clinical cooperative groups, the centers, the cadre of community physicians and the knowledge gleaned from research during the 1970s, we have the tools we need to undertake new directions in cancer control. I am referring to our Community Clinical Oncology Program (CCOP) and the new Cancer Control Research Units (CCRUs).

Cancer patients prefer to be treated in their home communities, and some 80 percent of cancer patients receive their primary care there. Through the CCOPs, we plan to supply resources to community hospitals so that they can be linked with the clinical research programs in the centers and regional cooperative groups. This will permit community physicians to enter their patients in clinical trials that develop and evaluate the latest cancer therapies. Because the treatment of different forms of cancer changes rapidly as new drugs, biologics, and radiation equipment become available, this new endeavor can have an enormous effect on the management of cancer patients in the United States. Through the newly established Cancer Control Research Units we plan to evaluate whether the benefit of the CCOP program will diffuse to those patients who are not participating in research protocols. We believe these programs will readdress a basic concept of cancer control envisioned in the 1971 Act; namely to bring the latest technology in cancer treatment to the community physicians and their patients.

Another cancer control program will take advantage of knowledge gained over the past decade in the fields of nutrition and prevention. These fields have burgeoned through the work of the many NCI-supported scientists, and we now have a wide array of leads to pursue and hypotheses to test. This information has led us to shift our prevention research to focus on interfering with the late stages of carcinogenesis, called promotion. Our previous emphasis was on substances that begin or initiate the cancer process. The strategy of interfering with promotion provides an opportunity to reduce cancer incidence more rapidly than the strategy of removing initiators from the environment.

The work of NCI and other scientists shows that synthetic forms of vitamin A, for example, can prevent the transition to cancer in cells already initiated by carcinogens. Cancer is chiefly a disease of older people. Interfering with the later stage of cancer promotion means that people age 50 or more, who already have been exposed to a number of carcinogens, very likely can benefit from this new information. We already have evidence from a "natural experiment" that such an approach can work: The incidence of cancer of the body of the uterus--a disease of older women--decreased in just a few years after women reduced their use of postmenopausal estrogens--a promoter for this form of cancer.

Many of the micronutrients found in our diet--vitamin A precursors, vitamins C and E, selenium and certain chemicals known as antioxidants--also act as "chemopreventive agents." Laboratory studies are further strengthened by population studies which suggest that people who eat foods high in vitamin A or its precursor, beta-carotene, have fewer cancers of certain kinds, such as lung cancer, even those individuals who have smoked cigarettes for a number of years.

Under the cancer control program, we are already testing the chemopreventive properties of the synthetic vitamin A compounds in two populations at high risk of cancer: women with early precancerous cell changes in the uterine carvix (cervical dysplasia) who often develop uterine cancer, and African albinos, almost all of whom develop skin cancer from exposure to sunlight.

We are also using the Act's general cancer control authorities to collaborate with the National Heart, Lung and Blood Institute to see whether beta-carotene can protect normal physician volunteers from developing cancer.

Beta-carotene, a precursor of vitamin A, is present in carrots, deep yellow and green leafy vegetables and yellow-hued fruit. It acts by quenching the very reactive, cancer-causing free radicals produced in our bodies as a result of normal metabolism. The Heart Institute is using the same population to see if aspirin can protect against heart disease. These studies represent the beginning of a new chemoprevention program that will give us a framework to evaluate other agents as they become available through basic research.

The new developments I have outlined are closely tied to advances in the field of basic biology that took place in the 1970s. Funds provided for the National Cancer Program have allowed us to increase the number of traditional grants by 265 percent, from 828 in 1971 to 2,191 in 1982. The revolutionary techniques of gene-cloning with recombinant DNA technology and the production of pure (monoclonal) antibodies with hybridoma technology--which are benefitting all areas of biomedical research--owe much of their origin and development to the expansion of the National Cancer Program.

These technologic advances have allowed cancer researchers to probe the very essence of the mechanism of cancer causation. For example, scientists recently isolated "cancer genes" from several forms of human cancers. When introduced into normal cells growing in the laboratory, these genes instruct those cells to become cancerous. The scientists believe there may be a specific gene associated with each different form of cancer. From previous studies supported by the Institute, we know that such genes existed in cancer-causing viruses, and those genes had normal counterparts in the cell's chromosomes. A likely explanation is that the viruses pulled these

genes out of normal cell DNA millions of years ago. From this evidence we believe that cancer may be caused by an "overdose" of normal gene products.

We are now using monoclonal antibodies in the diagnosis and treatment of cancer with some success. And with recombinant DNA technology, scientists cloned the human interferon genes. Human interferon can now be manufactured by bacteria in sufficient quantities to treat cancer patients. And the biologically-engineered substance is much purer than that made by conventional techniques. These are all products of research supported by the NCI and the NIH.

The legislative authorities for the cancer program have been instrumental in its successes, but good management is required too. After the period of rapid growth in the early 1970s, NCI required a period of consolidation. Since 1980, we have been taking a close look at the organization and management of the Institute's programs to improve its overall functioning. Such a look was necessary because with the increased activity stimulated by the legislation, priorities and opportunities in cancer research changed rapidly. Our management initiatives include:

- Clarification and expansion of the role of our advisory bodies; NCI differs from other institutes within the NIH in that each of its four programmatic divisions has an external Board of Scientific Counselors whose members are appointed by the division director. These boards oversee the division's programs and budgets. In addition to these boards, NCI has a National Cancer Advisory Board to review grants and to oversee the total program and a President's Cancer Panel. These two advisory bodies were provisions of the 1971 legislation, and their members are appointed

by the President. In addition, it is now NCI policy that each of the Boards of Scientific Counselors conducts a concept review of all contract projects proposed by the division it oversees. Each board knows its division's mission, programs, objectives, budget and resources, and has among its membership the scientific expertise needed to review proposed projects. In reviewing each project, new and old, and before voting approval or disapproval, the boards consider the goals of the proposed activity and what technology and other resources are available to achieve its goals. Through this process, we have been able to reprogram resources rapidly. The National Cancer Advisory Board oversees the deliberations of the Boards of Scientific Counselors by selected attendance at meetings, by reviewing minutes, and by an annual program review from each chairman and division director at the NCAB's November meeting. This system is unique at NIH in its involvement of non-government advisors in the contracting process at the project concept level. It illustrates the management flexibility the National Cancer Act provided to the NCI Director.

- Establishment of a budget formulation and decision-making process; We have developed a corporate approach involving top NCI staff to develop our annual budget. Our emphasis is to allocate funds in a way that will best serve the overall mission of the National Cancer Program.
- Contract cost analysis and fund reallocation; To emphasize reprogramming, we conducted an analysis of each of the Institute's 1,150 contracts during 1980 and identified $40 million of activities that could be reduced or eliminated. These funds were redistributed to

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new programs and to increase support of investigator-initiated research.

- Space review and analysis; We reviewed office and laboratory space and were able to reallocate resources to new programs at no increased cost. We also reduced the amount of rental space used by our intramural laboratories. Some of these laboratories were moved to our Frederick Cancer Research Facility.
- Review and justification of every NCI position; Through a position review, we changed staff allocations to match changing program requirements. This included reassigning staff to the new CCOP and chemoprevention programs I described. We also increased staff to monitor clinical trials of investigational drugs supported by contracts.
- Consolidation of business management; The Institute's executive officer is the focus of all business management. We transferred all program elements concerned with the administration of grants and contracts to his office. We transferred the technical review of all NCI contracts to the Division of Extramural Activities. Technical review for contracts is now patterned on the peer review process used for grants.
- Major revisions in the NCI contracting process; Revisions include a more extensive review process and closer monitoring. These changes are described in the book, The National Cancer Institute Contracting Process, which I would like to submit for the record.
- Reorganization of the Frederick facility; We reorganized the large contract that operates the Frederick Cancer Research Facility. We

reduced the level of effort by 20 percent and recompeted the contract as five contracts instead of one. We provided direct-line management from an administrator in my office through the principal investigator of the Frederick facility. This will mean better coordination with other NCI programs and will avoid duplication.

Through these management initiatives, we have been able to support the most important ongoing programs, to begin new programs to capture research opportunities, to phase out valuable older programs that had accomplished their purpose, and to eliminate unproductive and marginally productive activities. This is important because economic conditions have resulted in more frugal allocation of resources to NCI.

I have described for you how some of the remarkable achievements of the past 10 years are providing a framework for new programs. We are standing at the threshold of some very exciting times in cancer research, and we have a sound management system in place to capture these opportunities. The provisions of the National Cancer Act and the changes I have outlined have put the Institute in a most effective posture to face the exciting challenges in science we are already witnessing in the 1980s.

We feel the Act and its amendments have served us well over the past decade. It gave the NCI director the flexibility and authority he needed to carry out the Act's special provisions, while maintaining excellent and productive working relationships with the NIH. The maintenance of these authorities in their present form is essential for continuing the momentum of the National Cancer Program.

This completes my statement, Mr. Chairman. I will be pleased to supply additional information for the record.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20205

STATEMENT FOR THE RECORD

BY

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ACTING DIRECTOR, NATIONAL HEART, LUNG & BLOOD INSTITUTE

NATIONAL INSTITUTES OF HEALTH

BETHESDA, MARYLAND 20205

BEFORE THE

SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES

MARCH 31, 1982

Statement

By

Peter L. Frommer, M.D.

Acting Director, National Heart, Lung,

and Blood Institute

Mr. Chairman and members of the Subcommittee:

As the Acting Director of the National Heart, Lung, and Blood Institute, it is my privilege to present testimony to you. In the ten years since the enactment of the National Heart, Lung, and Blood Act, P.L. 92-423, the National Heart, Lung, and Blood Institute has achieved important advances in prevention, diagnosis, and treatment of diseases which are major causes of death and disability among Americans.

Scope of the NHLBI Mandate

Four of the ten leading causes of death in the United States are the concern of this Institute: heart disease (first), cerebrovascular diseases (third), chronic obstructive pulmonary diseases (fifth), and atherosclerosis (ninth). Together, these cardiovascular and lung diseases account for over 1 million deaths annually--over half the deaths in the United States.

Cardiovascular diseases are the leading causes of death in the United States for men begining at age 40 and for women beginning at age 60. These diseases account for 30 percent of all the potential years of life lost to illness. Approximately 40 million Americans have diseases of the heart and blood vessels. Furthermore, heart disease alone accounts for more bed days than any other condition. The total economic burden of cardiovascular disorders is estimated to be over $60 billion annually. This equals over one-fifth of the total cost of illness in the United States.

The social and economic toll of diseases of the lungs and respiratory system is equally severe and rising rapidly. They account for more than 5 percent of all the potential years of life lost as a result of illness. The total economic costs in 1980 for lung and related respiratory diseases was over $25 billion. This equals 8 percent of the total cost of illness, and 15 percent of all morbidity costs (second only to the morbidity costs of cardiovascular diseases).

Blood diseases frequently strike during childhood and standard economic measures cannot fully reflect the loss or costs in terms of suffering and grief. These diseases, including the hemoglobinopathies, cause or are manifested in a variety of serious disorders and their true impact is far greater than the mortality attributed to them. In those afflicted with serious chronic blood diseases, death is often attributed to acute superimposed conditions. In addition to the importance of blood diseases, blood and blood components play an essential role in general medical and surgical treatment, with 10,000,000 units of blood and packed cells used in the treatment of more than 2,700,000 Americans annually.

Strategy to Achieve the Mission

The program strategy employed for each of the disease-related mandates of the NHLBI consists of an ordered sequence: (1) acquisition of new knowledge, (2) testing, evaluation and validation of promising hypotheses and methods of treatment and prevention, and (3) dissemination of new and existing knowledge.

As the foundation of the Institute's program, laboratory-based research on disease etiology and pathogenesis receives the major portion of Institute resources. This research has yielded significant discoveries, concepts, and theories which, in turn, have become the bases for further research, development, and evaluation. When sufficiently refined and validated for clinical and public health application, the results are disseminated to the medical community and the public. Integrated within this continuum are other Institute-supported activities in applied research and development, clinical investigation, clinical trials, and in prevention, education, and control programs.

The Institute's strategy is aimed at maximizing the beneficial effects of research findings on clinical practice and on the health related behavior of the American public toward the ultimate goal of prevention. A detailed description of research accomplishments, planned activities, and program goals may be found in the NHLBI Director's Report, which is submitted annually to the President and the Congress.

Accomplishments

The past 10 years have seen major breakthroughs in the diagnosis, treatment and prevention of heart, lung, and blood diseases which are the result of discoveries made in a large number of studies of various kinds. Although newsworthy surgical and pharmacologic interventions have frequently provided evidence of recent accomplishments, it has been the strong, consistent program of laboratory and clinical studies that have provided the essential breakthroughs for each major advance. Each advance is dependent upon the accumulation of thousands of bits of knowledge. Research findings that allow for advances come from scientists working on fundamental and clinical studies in nearly every conceivable discipline from physics to pharmacology, and from biochemistry to epidemiology. Their work encompasses every stage of the biomedical research spectrum from basic research to prevention, education, and control programs and the transfer of findings to clinical practice.

Simultaneous with the broad advances in diagnosis, treatment, and prevention brought about by investigators in many disciplines is the substantial decline in cardiovascular mortality. Overall age-adjusted cardiovascular mortality has decreased by 30 percent and stroke mortality by 45 percent since 1968. The declining mortality rates are particularly encouraging among Americans of middle age; for those below 65, heart disease deaths (principally from coronary heart disease) have declined to rank third amongst all causes of premature death. Although the magnitude of these favorable changes has been beyond the expectations of 15 years ago, over one million Americans continue to die each year from cardiovascular and pulmonary diseases and deaths from chronic obstructive pulmonary disease have increased by 45 percent since 1968.

Laboratory-Based Research

The importance of lipoproteins and their apoproteins as cholesterol-carrying substances in the blood has been greatly clarified during the last decade. The role of these substances and their relation to risk of coronary heart disease (CHD) has been established along with other risk factors such as hypertension, smoking, and diabetes. Exciting recent findings have focused attention on the high density lipoproteins (HDL). Unlike the atherogenic low density lipoproteins (LDL), HDL has been inversely associated with CHD risk, that is, it is protective. However, cause and effect have not been established. Nevertheless, levels of HDL have been positively correlated with exercise and moderate ingestion of alcohol and inversely correlated with obesity, smoking, poor control of diabetes and the use of progestin-containing contraceptives.

Cystic fibrosis (CF) is one of the major pediatric pulmonary diseases in the United States. Although CF is known to be inherited, it is clear that the disease varies in severity, course, and outcome. Little is known about the underlying defect in CF or the extent of pathological alterations that mark the course of this disease, with the result that treatment is often ineffective. The mechanism underlying the susceptibility of patients with CF to pulmonary infections caused by Pseudomonas aeruginosa has recently been investigated. This chronic infection is responsible for most of the morbidity and mortality associated with CF. Studies have revealed that, although cellular and humoral immune mechanisms in general appear to be intact in CF patients, specific cellular immunity to Pseudomonas bactetrium seems to be impaired in patients with persistent Pseudomonas infection. In vitro studies indicate that peripheral blood lymphocytes from patients with advanced disease fail to respond to the Pseudomonas and other gram negative bacteria. This selective lymphocyte dysfunction in CF appears to correlate with progression of clinical disease. Related studies suggest that the severity of the pulmonary disease in CF is related to the altered adherence and affinity for bacteria of certain cells. These studies suggest that susceptibility to Pseudomonas infection may be a characteristic acquired during the disease state. They also provide a new understanding of the cellular defects underlying the infections and possibly lead to rational approaches to the amelioration or prevention of Pseudomonas infection in cystic fibrosis.

Cooley's anemia is a severe, hereditary blood disorder seen largely in persons of Greek, Italian, and Oriental ancestry and, to a lesser extent, in Blacks and Jews. The disorder begins shortly after birth. In Cooley's anemia, the production of hemoglobin within the red blood cell is impaired, causing severe anemia. Patients need transfusions for the rest of their lives to control this anemia. The repeated transfusions, however, cause the red cells to break down and deposit massive amounts of iron in the body tissues. Recent advances in iron chelation (iron-binding and -removing) therapy have been employed to correct this condition. However, reduced frequency of transfusions results in much less severe iron overload. New methods have been developed to obtain units of blood from normal donors that contain, primarily, young red cells (neocytes) having considerably extended lifetimes in the recipient. The use of neocytes extends the time interval between successive transfusions and consequently reduces iron overload. A technique of centrifugal density cell separation is used to quickly and effectively isolate neocytes from standard blood bank units at low cost.

Glycosylation of the hemoglobin molecule is increased in diabetic patients as a result of elevated blood glucose levels, and estimates of its extent can be used as a measure of long-term blood glucose control. Variant hemoglobins, with altered charge properties, are found in individuals with abnormal hemoglobin traits--such as sickle cell trait--and these produced misleading estimates of glycosylation in standard chromatographic assays. A new procedure, the thiobarbituric acid method (TBA) has been developed, in which a direct measurement of hemoglobin glycosylation is possible; TBA is uninfluenced by the charge on the hemoglobin molecule. Studies have shown that the TBA method is capable of producing reliable and accurate information about the extent of hemoglobin glycosylation--and hence blood glucose control--in all diabetic subjects, including those with abnormal hemoglobin traits, whose progress can now be monitored in a fully dependable fashion.

Validation of New Knowledge

New knowledge and promising hypotheses from research require validation before widespread introduction into the community. The most rigorous of validation methods is the clinical trial. However, clinical trials are expensive in use of biomedical expertise and research resources, and the number must, therefore, be limited to a few with the highest priority.

The last few years have brought outstanding results from clinical investigations that clearly demonstrated benefits from treating mild, moderate, and severe hypertension. In a recent clinical trial it was found that not only could good blood pressure control be achieved and maintained with drugs, but that adequate treatment prevented stroke, renal and heart failure, and probably heart attack as well. This clinical trial, the Hypertension, Detection, and Followup Program (HDFP) has been supported by the National Heart, Lung, and Blood Institute. The intervention phase of the trial was completed in 1979, and it demonstrated that a 17 percent decline in mortality is possible in a community setting through a systematic and aggressive approach to treatment of hypertension in community clinics in comparison with usual care. Even more dramatically, it demonstrated a 20 percent decline in mortality among aggressively treated patients with what is called "mild" hypertension. Furthermore, the study demonstrated that blood pressure can be brought down and kept down regardless of the initial blood pressure level, and that the ensuing health benefits applied about equally whether the subjects were male or female, young or old, black or white.

To observe whether the prognosis can be improved following a completed heart attack, the Beta-Blocker Heart Attack Trial (BHAT) was begun in June 1978. The specific objective was to determine whether long-term administration of propranolol (a blocker of certain effects of adrenergic stimulation) would prevent death following myocardial infarction (heart attack). By October 1980, 3,837 men and women, aged 30-69, with documented myocardial infarction within 5 to 21 days before entry into the study, were enrolled and randomized to two study groups, 1,916 to propranolol treatment and 1,921 to placebo treatment. Involved in the study were 31 clinical centers, a coordinating center, a center to read standard ECG's, a center to read 24-hour ambulatory ECG's, a central laboratory, a drug distribution center, and an NHLBI program office.

On the recommendation of the Policy and Data Monitoring Board, intervention was ended ahead of schedule on October 1981 instead of in June 1982 because early analysis of the data showed an unequivocal benefit from treatment with propranolol. Mortality was 9.5 percent in the placebo group but only 7.0 percent in the propranolol group, a reduction of 26 percent. The beneficial effects of propranolol occur primarily in the first year after a myocardial infarction.

Hepatitis-B Vaccine Trial: The first major clinical trial of a new vaccine to prevent hepatitis was completed recently. This Hepatitis B Vaccine (HBV) provides nearly complete protection against developing the debilitating disease, hepatitis type-B. The vaccine consists of highly purified, formalin-inactivated virus subunits derived from the plasma of chronic carriers of hepatitis type-B. For this study, a population of healthy young HBV-susceptible young men, relatively frequently exposed to the HBV virus, appeared to be the most suitable. Within one month of the first vaccination, 31 percent of persons receiving the vaccine developed antibody against hepatitis B; within two months, this rate increased to 77 percent; within three months, to 87 percent; and within six months, but before the third injection, to 90 percent. The booster injection increased the antibody response rate to 96 percent. Antibody response rates then remained essentially unchanged for the rest of the 18-month follow-up period. The development of the hepatitis B vaccine and the demonstration that such a vaccine prevents HBV infection are major advances in the control of this extremely widespread disease. Although most carriers of the hepatitis B virus are asymptomatic, a substantial proportion eventually develops chronic active hepatitis and cirrhosis. There is also overwhelming evidence that the hepatitis B virus is the single most important causative factor of hepatocellular carcinoma. Thus, mass immunization programs against hepatitis B virus infection should not only reduce the incidence of acute hepatitis B and the pool of chronic carriers, but also reduce eventually the morbidity and mortality from chronic active hepatitis, cirrhosis, and hepatocellular carcinoma.

Management of Patent Ductus in Premature Infants: Four hundred premature babies with patent ductus arteriosus, one of the most common congenital heart defects and a condition usually requiring surgical closure of a major heart vessel, were randomized into three treatment groups. The first group received early treatment with the drug indomethacin; surgical closure was used as needed when improvement or closure did not occur. The second group received usual medical care early, with indomethacin given only if spontaneous closure did not occur; surgical closure was used as needed. The third group received usual medical care with surgery as needed. Surgical back-up was provided for all patients so that proper treatment was withheld from none. The results of this trial show that on discharge from hospital 70 percent of babies receiving indomethacin had required surgery, but only 30 percent of babies receiving indomethacin required surgery.

Prevention and Education Activities and Transfer

To more rapidly bridge the gap between the laboratory and the daily use of knowledge in the practice of medicine, the Institute is directly involved in the dissemination of information and the direction of programs that prevent death and disability from diseases of the heart and blood vessles, lungs, and blood. A principal

example of such activities is the 10 year-old National High Blood Pressure Education Program about which the subcommittee has been informed in the past. This program is a unique private-public collaborative effort administered by the Institute to facilitate more effective control of high blood pressure in the United States.

We have built upon the relationships developed with the private sector in this program to stimulate additional cardiovascular risk reduction programs at the worksite. This effort is expanding and several major companies have developed related disease prevention and health promotion programs for their employees with assistance from the Institute. More recently we have emphasized work with the insurance industry which is not only instituting programs for their own employees, but also amplifying our joint efforts in prevention by promoting the programs among their numerous group subscribers. The subscribers are now adopting similar programs for their employees.

The Institute has worked with over 50 private sector organizations to promote risk factor reduction. Among these are: General Motors, Campbell Soup, Kimberly-Clark, Johnson and Johnson, General Electric, Ford, and Westinghouse. Insurance companies with whom the Institute has collaborated include Metropolitan Life, Travellers, Sentry, Massachusetts Mutual Life, and Blue Cross/Blue Shield. The Institute will continue to emphasize this effective collaboration.

Self-Management of Asthma: Asthma affects millions of children each year and continues to be the leading cause of school absenteeism. Attacks disrupt families and prevent participation in normal activities. The frequency of asthmatic attacks, however, can be reduced through self-management with the patient taking responsibility for the condition. A lack of medical compliance, failure to avoid known irritants such as dust, animals, or cigarette smoke, and inability to relax or to detect the onset, can precipitate severe attacks. The NHLBI has developed an educational program that has shown that asthmatic children and their parents can self-manage asthma successfully with a minimum of reliance on medical support. The results of a recent evaluation of the program show that children experience significantly less school absenteeism after enrollment in the program and parents report a 66 percent decrease in related health-care expenditure.

Tutorial Program for Children with Sickle Cell Disease: The Institute has developed an academic tutorial program for children with sickle cell disease or trait. The program is based on the concept that children with sickle cell anemia need special help to enable them to plan and manage their lives and to reach their highest potential. Ordinary educational systems are often not sufficient in this regard, and absenteeism and academic problems often result. Tutors with the program work together with administrators, teachers, parents, and agencies to encourage the afflicted child to remain in school, to develop normal friendships, and to grow in self-esteem.

Centers

The NHLBI Centers Program: To bring together the range of scientific and clinical expertise and resources essential to rapid progress in discovery of new knowledge and in application to clinical practice at the community level, the Institute supports three types of centers.

The Specialized Centers of Research (SCORs) provide a planned, coordinated national program of basic and clinical research focusing on the diagnosis, treatment, and prevention of specific diseases. Because of the unusually large adverse impact of arteriosclerosis, hypertension, ischemic heart disease, pulmonary disease, and thrombosis, NHLBI has given high priority to developing SCORs to study these problems. The Research and Demonstration Centers play a key role in the technology transfer process. They are specifically charged with applying the results of biomedical research to clinical practice. The centers encompass not only the two ends of the research-to-demonstration spectrum, but also the crucial juncture between new validated methodologies and the testing of their feasibility, acceptability, and amenability to use in existing clinical environments. In this sense the centers perform a vital investigative and educational function without which technology transfer could not proceed at an appropriate pace. The Comprehensive Sickle Cell Centers combine basic and clinical research, clinical trials, application training, and community service projects to bridge the gap between research and service in the area of sickle cell disease.

Training of Research Investigators

The achievement of progress in the Institute's programs is dependent upon the work of research scientists and clinicians who are well trained in a large variety of clinical and basic science disciplines. Many of the breakthroughs require diverse backgrounds to solve the complex problems within the legislation mandates of NHLBI. A Pulmonary Academic Award was designed and implemented to strengthen and enrich pulmonary medicine programs in medical schools. Minority health manpower recruitment for work in hypertension research has been facilitated by the Minority Hypertension Research Development Summer Program introduced by NHLBI. Research careers in the cardiovascular aspects of diabetes have been supported through establishment of Special Emphasis Research Career Awards. To encourage development of quality preventive cardiology curricula, Preventive Cardiology Academic Awards were initiated to attract outstanding students to the dual interests of preventive cardiology research and practice. To stimulate the development of research expertise in the methodologies of both clinical and basic science research, NHLBI established the Clinical Investigator Award. These more recent training programs are designed to complement our ongoing career development program and the institutional and individual fellowships which promote the growth of independent biomedical research expertise which is essential to progress against heart, lung, and blood diseases.

Problems Remaining to be Solved

The primary objective of NHLBI is to prevent diseases of the heart, lungs, and blood which, combined, cause widespread disability and premature

death among Americans. At the same time it is essential to improve treatment and rehabilitation for those who suffer from these diseases. The strategies available to achieve these objectives have proven successful, and the evidence indicates that the problems of cardiovascular, pulmonary, and blood diseases, complicated as they are, can be solved.

Opportunities for Investigator Initiated Research: One can only highlight and randomly pick from the broad range of important and highly promising areas of research in heart, lung, and blood diseases. The questions to be answered and opportunities range from molecular biology through laboratory investigation and clinical research to epidemiology, instrumentation, and technological development and research on the behavioral factors involved in the causation as well as in the management of disease.

For example, in the causation of arteriosclerosis, what is the role of lipids, lipid transport, and lipid receptors? In hypertension, what roles do obesity, sodium, stress and biobehavioral factors play?; and, how do coronary heart disease risk factors evolve and change in young adults? Why is there an altered response of the body to cardiovascular drugs at the ends of the age spectrum; in the neonate and in the elderly, particularly as it relates to pharmakinetics of heart failure and antihypertensive agents? In coronary heart disease, we must better understand rhythm disturbances, and the management of arrhythmias. We must elucidate the biobehavioral factors in the genesis of cardiovascular disease and the biobehavioral component of cardiovascular disease. Diagnostic methods need development ranging from immunoassays through computer enhanced imaging techniques and from a variety of noninvasive techniques to better pacing techniques.

In chronic obstructive pulmonary disease, the role of small airways in disease progression, the relationship of lung extracellular matrix interactions, the effectiveness of long term results of bronchial drainage are priority studies. Animal studies of new therapeutic approaches to interstitial fibrosis in the lung are opportune. For neonatal respiratory disease, we must assess the response of the immature animal lung to ventilatory support, a possible cause of lung injury. In the adult respiratory disease syndrome, the elucidation of pathogenesis and the development of therapy is paramount. An important area which needs attention is cystic fibrosis and its impact on the lung, including fundamental mechanisms of susceptibility to infection and most importantly, methods for identifying the asymptomatic carrier.

In a number of blood diseases, we need a better understanding of the molecular disorders of the hemoglobin and the mechanisms of their control. We need to examine the fundamentals of thrombus formation including the clotting sequence and the lysing sequence; the hemorhelogic aspects of thrombosis and hemostasis; and, the rheologic aspects of sickle cell disease. In Cooley's anemia we must do further research on the prevention of iron overload and decreased transfusion need, as well as education, and finally, the experimental use of perflurochemical blood substitutes in basic and applied research is of high priority.

The Systolic Hypertension in the Elderly Program (SHEP) is presently a pilot study of feasibility to investigate the efficacy of treatment for isolated systolic hypertension. This is a common problem in the population over 60 that is more highly prone to death and disability from cardiovascular disease. With continued successful operation of this program, a full-scale clinical trial will be considered for initiation in FY 1984.

The Use of Intra-Coronary or Intravenous Streptokinase in the Treatment of Acute Myocardial Infarction: Of particular importance at this time of high health care costs is this study to assess the possible effectiveness of intracoronary and intravenous thrombolytic therapy in the treatment of acute myocardial infarction. Over the last 18 months or so, there has been great interest in the use and efficacy of emergency cardiac catherization in patients with symptoms of acute myocardial infarction. In patients found to have occlusion of a coronary artery, the immediate infusion of an enzyme has been initiated, which often leads to the breakup of the coronary thrombus. The coronary angiographic changes as a result of this infusion are dramatic and there is a plausible rationale why there may be a net clinical benefit. However, there has been no study which establishes true clinical benefit in terms of lives saved or heart muscle being kept from irreversible damage. The procedure is moving toward widespread use without validation. It is one of significant expense and requires considerable resources, both in equipment and personnel. The Institute feels that an objective assessment of the value of this therapy is critically important.

Antiarrhythmic Agents in the Prevention of Sudden Cardiac Death: We are supporting a new pilot study on the use of antiarrhythmic agents to prevent sudden cardiac death in patients who have previously suffered a myocardial infarction. A substantial number of drugs have been shown to be effective in treating arrhythmias but their effectiveness in saving lives has not been proven. This is an important opportunity to take advantage of the pilot phase to set systems in place to perform a full scale trial if the pilot study proves the effort feasible.

Ventilation-Perfusion Scans and Pulmonary Angiography for Diagnosis of Pulmonary Embolism: Pulmonary embolism is a condition thought to be associated with at least 50,000 and possibly a substantially larger number of deaths annually. The current standard technique for diagnosing pulmonary embolism is plumonary angiography. This trial will assess the accuracy of ventilation-perfusion scans, a radionuclide imaging technique in diagnosing pulmonary embolism, which, as a non-invasive technique is less dangerous and less costly than pulmonary angiography.

Several other Institute initiatives are under consideration on topics requiring Institute direction and coordination: further studies on the role of sodium intake in the causation of hypertension, including possible corollary studies on the possible protective effects of potassium; prostaglandin metabolism and thromboatherogenesis; the role of specific lipoproteins in atherogenesis; calcium blockers in the management of coronary spasm; studies of heart disease in the young; behavioral factors in the genesis of cardiovascular disease and the biobehavioral component of cardiovascular disease management; rehabilitation and emotional

adjustment in chronic obstructive pulmonary disease; the response of immature lungs in the response to ventilatory support; the relation of microanatomy and pulmonary function; the assessment of the clinical efficacy of components of human serum albumin; the development of sources for anti-hemophilic factor free of hepatitis viruses; hemorheologic aspects of thrombosis and hemostatisis particularly in relation to sickle cell disease; and the implementation of a community surveillance system for cardiovascular and other chronic diseases.

Finally, demonstration and education activities, particularly in prevention, are of paramount importance. We are considering special initiatives in these areas as well as in health education activities, especially with regard to smoking and nutrition.

In summary, Mr. Chairman, I have characterized the problems presented by diseases and conditions of the cardiovascular, pulmonary, and blood systems in the U.S., and I have described some past accomplishments and some proposals for future efforts by the National Heart, Lung, and Blood Institute. I would be pleased to respond to questions or to provide reference materials for the record.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20205

STATEMENT FOR THE RECORD

by

Martin M. Cummings, M.D.
Director

National Library of Medicine
National Institutes of Health
Bethesda, Maryland 20205

before the
Senate Committee on Labor and Human Resources

March 31, 1982

MEDICAL LIBRARY ASSISTANCE ACT

OPENING STATEMENT

The Medical Library Assistance Act of 1965 responded to a national need for improved library services. The growth of medical research and education with a corresponding increase in published literature led to demands for information services which could not be met by the nation's medical libraries. This information explosion is the natural outgrowth resulting from the successful investment in biomedical research. Prior to the enactment of the authority there were no mechanisms available to assist health science libraries. Several important studies concluded that a national program for medical library improvement was urgently needed.

The MLAA authorized the establishment of grant and contract programs which are administered by the National Library of Medicine. The Act assists in the development of a Regional Medical Library Program which provides access to health care and biomedical information, assists in the improvement of basic library collections and resources to make the collections more readily accessible, supports research in improving information transfer to health care practitioners, supports training programs that teach health professionals how to exploit computers in medical applications, provides support for health science publications which are not commercially feasible, and supports distinguished scholars in writing treatises on major health subjects. The Act has resulted in the improvement of library services and established an effective national medical library network.

Through the Regional Medical Library Network 3,000 health science libraries at academic, health care, and research institutions, make information services available to health professionals regardless of their location. The RML program is a partnership that has effectively and efficiently implemented programs of cooperation and resource sharing. The RML funds awarded have always supplemented, not supplanted existing resources.

A management evaluation of the Regional Medical Library Program was completed recently, leading to the decision to reconfigure the network to achieve greater efficiency and cost-effectiveness. In 1982, the present eleven regions will be reduced to seven through a competitive contract process. We believe that no loss in efficiency will result as new technologies make networking more effective.

Although the health library community is well along in creating a national library network, much remains to be done. Many smaller health institutions, serving large numbers of professionals, are without adequate library resources and services. Some libraries are still lacking a full range of services, and have not benefitted from modern communications technology. NLM's extramural grant programs will continue to provide needed support for these libraries.

The volume of biomedical information continues rapidly to expand and the systems to handle data grow correspondingly sophisticated and complex. The Computers-in-Medicine Program supports studies of new applications of computer technology in health care settings, of decision-making processes in health practice, and of new ways of assisting health professionals to draw upon health knowledge and research results in the evaluation and management of disease. Studies include basic research into fundamental issues of health information, as well as the improved application of research findings. Many of the principal investigators supported by these MLAA grants are becoming the leaders of this important field.

The ultimate goal of the training program is to promote the effective integration of computer technology into all phases of clinical medicine. The NLM's training program is the only federally supported effort designed to augment the manpower pool in medical computing as it relates to the information sciences.

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Research grants support activities leading to new knowledge about health information access, retrieval, and use. For example, one researcher has developed a computer program based on NLM's MEDLINE citations that provides an inexpensive and efficient means of searching for literature known to be held locally and thus immediately available. This system is rapid and easy for the hospital staff to use when more exhaustive searches of MEDLINE are not required. The achievements of this system have resulted in requests for its utilization at other hospitals.

The publications grant program of the MLAA has provided for the support of selective, high quality, non-profit biomedical publications important to medical progress and public health. Over 76 major book length studies in the biomedical sciences and numerous articles, bibliographies and biomedical reference tools have resulted from these awards. The grant program has emphasized the critical review, a scholarly comparison and assessment of information available in a particular subject area. Historically, these reviews have provided physicians and scientists with the best medical judgment on the value and limitation of new scientific work.

The national investment in medical research and development is realized only to the extent that the results, information and new knowledge are known and utilized. Sixteen years of experience with the Medical Library Assistance Act have shown that the information needs of the total health community--scientists, educators, practitioners, students and administrators--can be effectively and efficiently served by a coordinated health information program and a national health science library system. The MLAA enables NLM to develop information access mechanisms linking individuals and institutions at local, regional and national levels. The conditions of information need that gave rise to the MLAA are still very much present. There is a need to reauthorize these programs so the efforts they support can continue.

The CHAIRMAN. Thank you so much, Dr. Brandt. Thank you for your testimony.

I share your view that the reauthorization of the activities of the NIH is a vote of confidence on their work. However, as an elected representative of our citizens, I am concerned that the great sums of money that we authorize for biomedical research be used as efficiently and as effectively as possible.

Oversight hearings on the National Cancer Institute held last year brought evidence to light that the funds have been mismanaged, at least in part, and I am certain similar problems have occurred in all of our institutes because they are big and they are difficult to manage.

What steps have been taken to prevent waste of taxpayers' dollars by funding questionable projects?

Dr. BRANDT. We have taken several steps to look at that whole problem, Senator Hatch. I think, one, as you know, the process whereby decisions are made as to which projects get funded is a complex one. It involves both the councils of the institutes as well as initial review groups, as well as the staffs of the NIH and the scientific community generally.

Basically, what we are seeing now is that the quality of applications that are coming to us has risen considerably in the past 10 years, as one would expect with increased numbers of people out there. There has been an expansion of the pool of people for selection by the four review groups and four councils, so that after the priorities are set, these people review, and then we can feel reasonably comfortable, I think—as a matter of fact, quite comfortable—that the research that is being supported is in fact high quality and making a contribution.

Dr. Malone may have additional comments.

Dr. MALONE. Yes, thank you, Dr. Brandt.

Mr. Chairman, I am glad that, in the other statements, we have a perspective for this question, that one has to look at, on the one hand, the remarkable achievements in biomedical research. Indeed, I think that since World War II America's contribution to civilization has been what has been accomplished in biomedical research, and we are indeed in the midst of biological revolution.

I think, in an establishment of that magnitude, it is inevitable that one would have some problems. In the case of the cancer institute, suddenly, in 1971, there was a great escalation in funds, in programs, in expansion of activities, and there had to be a rapid adaptation to that sudden shift in time-limited activities, contracts, clinical studies, and the like, and that quick shift indeed did result in some inequities and deficiencies in management. They were quickly corrected by, first of all, the origination of a committee to review the contract procedures under Dr. Cooper, and, subsequently, every institute Director has brought about management changes.

I think Dr. DeVita has been most acute in this area. He has increased efficiency by reorganization, has established a very intense process of decisionmaking. Just in 1980 he analyzed over 1,000 contracts and reduced or eliminated somewhere between $30 and $40 million of those that did not come up to the level of quality and has indeed transferred many of the contract projects over to the

grants which are now becoming reviewed through the grant peer review process.

I think we have strengthened both the contract and the grant review processes so that they now are equal in attention to that peer review process. I think one will find this now occurring across the NIH in an attempt to prevent any wastage of the taxpayers' dollars, as you put it.

The CHAIRMAN. Thank you.

Another major concern we have heard comes from our universities regarding the proposed 10-percent reductions in institutional support which of course is provided by indirect costs in grants and contracts. There is also a significant difference of opinion among institutions and research scientists regarding just how much of the NIH budget should be spent to indirectly support our universities, with "indirectly" probably in quotes.

What is being done to address these concerns, and have you considered establishing some regulations to make indirect costs more uniform?

Dr. BRANDT. Mr. Chairman, I had the opportunity to read your statement as you introduced this bill yesterday and your request of us that we reconsider the issue of indirect costs and particularly the 10-percent cut. I want to assure you that you are not the only one that has made that request of us, and we fully intend to follow up on it.

Indirect costs are real costs, and I think we have to recognize that. It is not really an indirect support of the university in one sense. It is in fact a way to pay the total cost of the research.

Through the past few years, because of the budgetary constraints, the direct costs have been cut and indirect costs have continued to rise so that they now consume nearly 30 percent of the total cost NIH extramural research.

We believe that that must be addressed. Precisely how to do that, I think, is something that we are open to suggestions and open to other considerations. This was a way to at least start, and it was a way to say that since the researchers have been absorbing the bulk of these costs in the past that perhaps the institutions ought to look and see if there was some way that they could absorb some of it as well.

In any event, I think the issue of whether we can make indirect costs uniform gets into the whole area of accounting systems used by universities. Clearly, we would like to make it more uniform than it currently is. We appreciate also, I might say, your comments concerning the proposed changes in 821 in response to OMB, because I think that is one step toward getting things in better shape.

The CHAIRMAN. I am going to submit the rest of my questions to you except for—let me just ask you one more.

Dr. BRANDT. All right, sir.

The CHAIRMAN. We hope you will answer these as quickly as possible.

Dr. BRANDT. Yes, sir.

The CHAIRMAN. But one more oral question. In cooperation with the administration, we have proposed, as you know, eliminating

the presidential bypass of the NCI budget. Why do you believe this is important?

Dr. BRANDT. I think the question can probably best be answered as a matter of principle, and it has to do with your concern about whether the NIH is an institution, on the one hand, or a collection of institutes, on the other hand.

I, as you know, was the dean of a medical school, and I certainly would not have been comfortable had my Department of Surgery been able to submit its budget to the president of the university and bypass me as the dean, any more than I think any division of the National Cancer Institute ought to be able to submit its budget directly to the Secretary without going through the head of the National Cancer Institute.

So I think it is a principle of management that the person who is responsible—namely, in this case, the director of the NIH—be permitted to make modifications. It permits us to do some trans-NIH priorities that I think are important to us in the future, particularly with tight budgets.

The CHAIRMAN. Let me turn to you, Dr. DeVita, and let me ask you this. Many reports have indicated that we are on the threshold of a major breakthrough in cancer research because of recombinant DNA and monoclonal antibodies. Could you explain to the committee why this may be so important?

Dr. DEVITA. Well, at first the technologies themselves were very important just because of the potential they had. Now they are being used in laboratory experiments to advance our knowledge of the mechanism, of the cause of cancer. The last 6 months have been rather exciting, in a sense. We know we have approximately 15 cancer genes that were first identified in what we called retroviruses and thought to be viral genes. All these genes, by the way, have been tracked using these technologies—cloned and precisely identified.

We have found out recently that these genes are perfectly normal human genes that were probably pulled out of the human cell millions of years ago, and it is the way they are inserted into the normal cell that allows it to become cancerous.

Now, the exciting thing that has happened, literally in a matter of weeks, has been that some scientists using a new technique called transfection have taken cancer cells from humans—bladder cancer, colon cancer, breast cancer—taken genes out of those cells, put them into mouse fibroblasts growing in culture, and have converted those cells to cancer cells, and they have been able to identify these genes and sequence them. So now we are getting a pool of genes that we can identify as the causative factors in cancer.

The most recent and the most exciting piece is that there is some homology; that is, there is some familiarity between the genes that have been found in bladder cancer and colon cancer with the genes that were found in these retroviruses.

So if the pool of genes is 15 to 100 in size, we can perhaps deal with that in terms of mechanisms of cancer very shortly.

The CHAIRMAN. I have a number of other questions for you, and of course one of the more important ones is, during the hearings last summer, several problems of NCI were discussed. Perhaps I should ask for this in writing so we could have you really reflect on

it, but I would like you to briefly explain—or exhaustively explain, I guess, would be a better way—what has been accomplished to address the two major concerns that we raised at that time, and that is, what are you doing to tighten control of the grants and awards programs and contracts?

Also clinical trials using unproven chemotherapeutic drugs in terminal cancer patients, what are we doing to better control these research programs with human subjects? I know you can answer that orally here today, but why don't I submit that and a number of other questions to you in writing, and I think it would be beneficial to the committee for you to answer those questions, and I think, from what I have seen, there have been some significant changes. We probably need a follow-up hearing to give you the full time in public to be able to explain that because of the nature of the hearings last year and the difficulty of those hearings.

Dr. DEVITA. I would be delighted to do both.

The CHAIRMAN. Personally, I have appreciated the efforts you have put forth.

Dr. DEVITA. Thank you very much.

The CHAIRMAN. And I think you have to personally appreciate that, as bombastic in some ways as those hearings were, nobody was calling for radical changes up here on the Hill. We want to see the National Cancer Institute function and work well. Frankly, I have a lot of admiration for you as a scientist. We will just have to see what changes have been made and what really has happened. So I will submit that and a number of other questions to you in writing. If you could have your answers back in a relatively short period of time, we would appreciate it.

Dr. DEVITA. Certainly.

The CHAIRMAN. Dr. Frommer, your institute must respond to the research needs of a variety of disease processes. According to law, the amount of money allocated to the lung or blood program is not to be less than 15 percent.

Can you tell the committee what percent of your current budget is actually designated for each of these programs, and how are the decisions made?

Dr. FROMMER. Mr. Chairman, at this time, in fiscal year 1982, we foresee about 17 percent of the budget in lung, about 16 percent in blood, and the balance, of course, 67 percent, in heart.

The method by which the decisions are made is looking at the research opportunities that exist. These come in two major forms. One represents the investigator-initiated grant applications, which represent the bulk of our applications, and there we make sure that we pay to the same percentile, the same extent down the scoring system. The second is initiatives that the Institute undertakes, and here we have a detailed system in which we have advice from the scientific community identifying needs and opportunities for research.

These are then reviewed by advisory groups, by divisional staff, iterated, brought to the Institute, put into priority order, presented to the National Heart, Lung and Blood Advisory Council, and it is only after their advice and concurrence that we put forth our Institute initiatives, and these achieve balance according to where the needs and opportunities are in heart, lung, and blood research.

The CHAIRMAN. Thank you.

I have a number of other questions for you which we will submit in writing as well, and if you can get your answers back quickly, we would appreciate it.

Dr. Cummings, last year this committee discussed the issue of what the library should charge for his products. On the one hand, members of the industry are complaining that the library is unfairly competing with them. On the other hand, the library community argues that many institutions could not afford to pay full cost. I proposed last year what I thought was an adequate compromise. Nonprofit institutions could continue to be subsidized while for-profit corporations such as the drug industry would pay the real costs of the library's products.

The library opposed this solution, believing in "equal access for all." Now, in attempting to find a fair solution, I have asked the OTA, the Office of Technology Assessment, of which I am a board member, and the GAO to study this problem, and I will expect their reports quite soon.

Do you have any suggestions on how we could resolve this issue on an equitable basis?

Dr. CUMMINGS. I am pleased to be given this opportunity to suggest a method to resolve this important issue, Mr. Chairman.

First, may I say that your earlier interest in the problem has already stimulated reviews other than those that you have requested. Particularly, I would like to report that your interest stimulated a review by our own board of regents. As a result of their deliberations, we have already increased the level of our charging by 35 percent for non-prime-time computer service and by almost 50 percent for use during prime time.

The result of these changes in charging now leads to the following, namely that we are recovering full accessing costs for on-line services and total cost recovery for the leasing of our tapes, which places us, I think, very close to the position that you suggested last year.

I should say that we have also sought advice from other groups including user groups like the American Medical Association, the American Library Association, and the Association of American Medical Colleges.

I would like to be able to report that, as a result of these changes, we find ourselves in an interesting situation where hospitals, particularly small hospitals, now complain that our charges are too high, whereas at least one large commercial vendor still maintains that our charges are too low.

So we continue to find ourselves sort of in the middle, and I thought I should at least account for the changes that we have made since your interest last year.

The CHAIRMAN. Thank you so much.

I have a few more questions for you, also, which I will submit in writing.

Senator Hawkins asked me to ask you to stick around because she has some questions. I think we will know whether she is about to be back here in the next 5 to 10 minutes, and in the meantime, I will ask her staff members to call and see if she can come right over.

I am going to submit the rest of my questions in writing, and I apologize that this has been such a long morning, into the afternoon, but it is just the way it is, and there is nothing I can do to change it. Unfortunately, we go through it all the time, but you don't have to unless you come up here and testify all the time, and some of you do. I know you, Dr. Brandt, are somewhat used to it.

[The information referred to follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

26 APR 19[illegible]

Dr. David Sundwall
Committee on Labor and Human Resources
United States Senate
Dirksen Senate Office Building, Room G-237
Washington, D.C. 20510

Dear David:

Enclosed are responses to the questions Senator Hatch sent to Dr. Brandt on April 1 to be included in the record of the March 31 hearing on the Biomedical Research, Training, and Medical Library Assistance Amendments of 1982.

If we can be of further assistance, please let us know.

Sincerely,

Tom

Thomas M. Antone
Deputy Assistant Secretary
for Legislation (Health)

Enclosure

1. I share your view that reauthorization of the activities of the NIH is a "vote of confidence" in their work. However, as an elected representative of our citizens, I am concerned that the great sums of money we authorize for biomedical research be used as efficiently and effectively as possible. Oversight hearings on the National Cancer Institute held last year brought evidence to light that funds have been mismanaged, and I'm certain similar problems have occurred in all of the Institutes. What steps have been taken to prevent waste of taxpayers' dollars by funding questionable projects?

   Answer: The process by which NIH makes funding decisions has traditionally sought to prevent funding "questionable projects." The peer review system subjects each application or proposal to rigorous evaluation for scientific merit. Further consideration by advisory councils and boards and by program staff introduces additional criteria of program relevance and balance.

   NIH has taken additional steps to strengthen the post-award review of projects it funds. For example, a recent GAO study found that documentation of staff review of annual progress reports could be improved, and NIH is developing a format for use by all BIDs. Recent experience with investigations of misconduct on the part of awardees has led to efforts to develop ways of dealing with on-going awards when the integrity of the investigator or the validity of the research are in doubt. To date, these actions have been taken on a case-by-case basis and have included: partial suspension; withholding of non-competing awards; deferral of an award pending completion of an investigation; and imposition of special conditions or prior approval requirements. NIH is currently expanding and refining its procedures for dealing with problems arising in the course of an award and for determining the extent to which NIH knowledge of alleged or actual misconduct should influence future awards. NIH believes that decisions related to scientific merit and program relevance are best handled through the traditional review and award process.

2. Another major concern we have heard from our universities is the proposed 10 percent reduction in institutional support which is provided by "indirect costs" in grants and contracts. There is also significant difference of opinion among institutions and research scientists regarding just how much of our NIH budget should be spent to "indirectly" support our universities. What is being done to address these concerns? Have you considered establishing some regulations to make indirect costs more uniform?

Answer: The 10 percent reduction in indirect costs that we have proposed is a reflection of two problems NIH is faced with. The first is the constant escalation of the indirect cost rates themselves and the second is our commitment to the Congress to award a stipulated number of new grants annually. We find that we cannot begin to approach this commitment in FY 1983 unless we somehow reduce the funds paid to grantees to cover indirect costs.

The problem of the escalating rates is a difficult one to deal with and DHHS is exploring the various alternatives which might be pursued. These alternatives have been discussed at various times with representatives of the university community, OMB, and the Office of Science and Technology Policy. We have not as yet reached any conclusions as to how we might eventually proceed, but we are trying to be responsive to the desires of the Congress to reduce administrative costs, to the research community to maximize the amount of funds available for the performance of research, and to the institutions to minimize the effect, to the extent possible, of any changes to our indirect cost policies. It should be noted that the 10 percent reduction is viewed as an interim action.

3. There has been a lot of press over the past year about "bad research," dishonest scientists, and downright fraud in research. Do you think this is a major problem? What is being done about it?

Answer: There is no doubt that more cases of misconduct in science are being reported. While the numbers are not large in terms of the total number of active projects, the consequences are serious for an enterprise rooted in the pursuit of truth. As noted in response to the previous question, NIH is taking a number of steps to refine and expand its policies and procedures. This process will include discussions with investigators and institutions in recognition of the fact that the investigators and institutions play a vital role in ensuring the integrity of the research enterprise. NIH believes that the increased reporting of apparent misconduct reflects in part an increased sensitivity within the community.

4. Evaluating the tremendous number of grant applications that NIH receives each year must be an arduous task. While there appears to be general acceptance that the NIH peer review system is one of the best means of appraisal, many of the chronic complaints such as the "good old boy network" suggest the system could be improved. Could you briefly describe the selection, function, and work load of peer review groups and then explain what steps, if any, have been taken to ensure the objectivity and efficiency of these groups?

Answer: The peer review groups are panels of experts organized along the lines of scientific disciplines or current research areas for the primary purpose of evaluating the scientific and technical merit of grant applications. Members are selected primarily for their demonstrated competence and achievement as independent investigators in a scientific or clinical discipline or research specialty, but also for such personal characteristics as mature judgment, objectivity, and personal integrity to assure the confidentiality of applications and discussions and the avoidance of real or potential conflicts of interest. Additional consideration is given to the avoidance of concentrations from a particular geographic area or institution. Special efforts are made to find qualified women and minority members.

Appointments are for 4 years and the terms are staggered; therefore, each year there is a turnover of one fourth of the membership. The NIH publishes semiannually, and distributes widely, membership rosters of its advisory committes. In addition, all principal investigators automatically receive at the completion of the review process the critiques of their grant applications, accompanied by a complete list of the membership of the reviewing groups. Applicants thus know the reviewers of their applications.

In Fiscal Year 1981, NIH peer review groups reviewed 22,439 grant applications, more than twice the number reviewed in 1973. The NIH has responded to this staggering increase in workload in a number of ways: simplifying the application form and limiting the size of applications, adding extra staff, chartering more review groups, introducing automated technologies, and making organizational changes. While these efforts have improved the efficiency of, and eased the burden on, the peer review groups, additional measures need to be taken in the future to manage the workload.

The procedures explained above were designed to foster the objectivity and efficiency of its peer review groups; but the NIH also ensures that members adhere to strict conflict of interest procedures designed to prevent favoritism, or the appearance of favoritism, in the peer review system. When an application is received by NIH from a member of a review group, or from any close relative or professional associate, it must be reviewed by a different group from that on which the applicant investigator is serving. Also, members must leave the meeting room when any application from their own institution is being discussed or reviewed. If the member has any possible financial interest in an

application, he or she must be absent from its review. The same holds for any situation where there might be a personal conflict of interest, such as an application from a mentor or from a former student. Following all review group meetings, all members must sign a formal certification that they absented themelves from, and were not involved in, the review of any application when such participation would have constituted a real or apparent conflict of interest.

Along with these specific guidelines, an extraordinarily effective control on conflicts of interest is the face-to-face panel meetings required of all NIH review groups. In these meetings, evaluations of proposed research are conducted under the scrutiny of 15 to 20 peers and several NIH staff members, all of whom are sensitive to avoiding even the appearance of conflict of interest. Considerable social pressure is generated in such a setting to be scrupulous in shunning decisions based on considerations other than scientific merit.

In recent years, the peer review system has been examined in no less than 16 different reports by various committees, most of whom are non-NIH and chartered by the Congress, the professions, or the Executive Branch. All of these studies have found the system basically sound. In addition, as other advanced nations have attempted to develop their scientific capabilities, most have adopted some form of peer review, frequently modeled on the NIH system, as the keystone for the selection of science to be supported. Clearly the NIH has created as effective and equitable a system as possible, one that has received the respect and admiration of scientists in the United States and elsewhere in the world, but one that is constantly being modified in response to changing conditions.

5. It is my understanding that research projects may be supported by either grants or contracts. Could you explain how specific projects are developed for contractual awards and clarify the differences between contracts and grants in terms of peer review, indirect cost rates and participation of "for profit" organizations?

Answer: It is true that NIH research projects are funded by grants and contracts, and also by cooperative agreement awards.

NIH research and development contract awards conform to requirements of the Federal Procurement Regulations (FPR) and DHHS Procurement Regulations (HHSPR), as well as additional PHS and NIH R&D contract policy and procedure guidance. PHS regulations require scientific peer review of the concept of R&D contract projects before public solicitation. A qualified scientific peer group of advisors, comprising not less than 75 percent non-federal employees, must review the scientific concept of the proposed project, taking into account the scientific or technical significance of the activity; availability of the technology and other resources to achieve the goals; and the identified uses for the anticipated results of the activity. Scientific program managers reach final decisions whether to proceed with the project, based on this peer review group advice.

The subsequent open competitive process follows further from FPR and HHSPR requirements. All contract opportunities are announced in the Commerce Business Daily and, for most solicitations, also in the NIH Guide for Grants and Contracts, an NIH publication with more than 18,000 recipients. Requests for proposals (RFPs) are mailed to organizations which respond to these announcements, and to other sources known to be capable of performing the proposed work. The RFP contains all the scientific and business information necessary to enable prospective contractors to prepare proposals.

The proposals are evaluated by NIH from both scientific and business standpoints. If the project involves innovative or original approaches, the proposals must receive full peer review. After the ranking of initial proposals the NIH holds competitive written and/or oral negotiations with all offerors having a reasonable chance to be selected for award; site visits for these discussions often involve peer review advisors. Following completion of these negotiations, the offerors submit revised proposals, which NIH evaluates further, sometimes again with the help of peer review advisors. Final recommendations then lead to selection of the contractor(s) based on best technical and cost advantages to the government.

Grant reviews start with the receipt of applications from applicant organizations. The applications are reviewed first by scientific peer review groups, referred to as "initial review groups," which evaluate the scientific/technical significance and originality, adequacy of methodology, qualifications and experience of the proposed investigators, availability of resources necessary for the work, and reasonableness of requested budget. Summary statements

reporting the results and recommendations from these reviews, are then reviewed by the national advisory councils and boards of the respective institutes or divisions, to add recommendations on the significance of the applications to the program policies and priorities of the institutes. Program managers base the eventual grant awards on these combinations of advisory inputs.

There are essentially no real differences between indirect cost levels for NIH grants and contracts. A recent study by the Division of Contracts and Grants revealed that indirect costs constituted 27 percent of the total costs of NIH FY 1981 contracts, while they were 28 percent of the total costs of grants. Recent developments in HHS and PHS regulations now leave no differences between nonprofit and "for-profit" organizations with regard to their eligibility for NIH grants. The one major difference between grants and contracts reflects the requirements for their use as award mechanisms as dictated by the Federal Grant and Cooperative Agreement Act, P.L. 95-224, i.e., grant awards reflect an assistance relationship between the NIH and recipients; contracts reflect an NIH acquisition or procurement purpose.

6. As we prepared for these hearings, a concern was frequently voiced from several research groups that a career in biomedical research is becoming less attractive to our young scientists because of relatively low pay, and what is perceived as fluctuating federal support. These young scientists reportedly view a career in biomedical research as insecure. How do you propose we create a sense of security and guarantee the best and brightest of our young scientists will continue to devote their energies to basic research?

Answer: A recent study reported by the National Academy of Sciences described the results of a study on career determinants for physicians deciding to enter clinical research. The three factors of highest importance were the opportunity to work in the academic community, the challenge of the research for new knowledge, and research experience while a premedical or medical study. A fourth factor was the availability of research training support. It was reported that the medical scientist training program of NIGMS (M.D.-Ph.D.), the research associate and clinical associate programs at the NIH, and the trainee/fellowship programs supported elsewhere were all highly successful in producing physician investigators. NIH will continue to emphasize clinical research training through these mechanisms and expects to maintain, if not increase, the number or clinical postdoctoral trainees.

The most important determinant of all, however, may well be the assurance that support will be available after the arduous 5-7 year research training period for well qualified investigators. A realistic stabilization of the number of new and competing awards will assure the potentially best and brightest of our new young scientists that the future funding picture will permit them to do the research for which they have trained.

7. In cooperation with the Administration, we have proposed eliminating the "Presidential bypass" of the NCI budget. Why do you believe this is important?

Answer: Section 404(a)(8) (A) and (B) of the Public Health Service Act authorizes a special budget process for the NCI which is different from the other NIH Institutes. This provision was added with the passage of the National Cancer Act of 1971. Under the law, NCI submits, in effect, its budget directly to the President. The current process permits review and comment of the NCI budget by the Secretary, and Director of NIH, but does not permit those officials to change the request.

In the early years following the passage of the Cancer Act, the budget bypass provided a means for putting forward a "professional judgment" budget and probably did contribute to the growth of the cancer program. Although, in recent years, the existence of a separate budget for NCI has not influenced the development of the President's budget, it continues to require the time and effort of both NIH and other Departmental staff.

As you know, the Department has proposed to repeal the bypass.

8. The Administration has made a concerted effort to highlight preventive medicine and health promotion. However, critics of our health policy are quick to point out that the focus of our greatest investment, that is, funding of biomedical research through NIH, has been almost entirely focused on treatment or cure of disease. What is being done to increase the research effort in preventive medicine?

Answer: The statement that NIH focuses almost entirely on treatment and cure is not correct. Throughout its 95 year history, prevention has been a main objective of NIH research. The decline in mortality for heart attacks and stroke can be traced directly to research on high blood pressure and blood lipids (fats). NIH supported the fundamental virology and cell biology research that made new vaccines possible between 1955 and 1975. These new vaccines, poliomyelitis, measles, mumps, and German measles are estimated to have saved the public $4 billion dollars in 1980. One Institute, the National Institute of Environmental Health Sciences, spends 60 percent of its budget on the identification and control of toxic substances in the environment. The largest percentage of NIH supported research is basic, directed at funding new knowledge needed for prevention and treatment of the many diseases that can not now be prevented.

9. Research equipment is growing obsolete across the nation. The equipment shortfall is estimated at $500 million. Recent reports warn all of us against the growing scientific instrumentation deficit if the nation is to retain leadership in science and engineering and to solve the problems of industrial productivity, agriculture, health care and national defense. How do you intend to deal with this problem? Is there any incentive in the indirect cost category for universities to invest in equipment?

Answer: NIH has always provided the funds for equipment needed to carry out approved investigator initiated research. A recent study of research project grants has shown that 76 percent of the funds awarded in the equipment category in FY 1979 were for less than $10,000. It is felt that the system provides reasonably well for most instrumentation needs at the project level.

Several studies have documented the fact that equipment shortages do indeed exist for instrumentation costing in excess of $30,000. Recognizing the increasing need for instrumentation, the National Institute of General Medical Sciences (NIGMS) announced in FY 1979 a shared research instrumentation program for NIH grantees, of whom at least half were required to be NIGMS grantees. Each award funded the purchase of instruments or instrument clusters with a capital cost greater than $40,000. The maximum award was limited to $150,000, included in which was $15,000 per year for a period of three years for operating and maintenance costs. Proposals requesting $26 million were received. Available funds allowed a total of approximately $9.0 million of awards to be made in FY 1979 and FY 1980. The program was reannounced in FY 1981 for instruments with a capital cost greater than $30,000 and a limit of $200,000 per award. All other features were the same. Proposals requesting $15 million were received in response to the reannouncement of what has now been made an ongoing program.

In an effort to meet the needs of others in the NIH research community, DRR announced a shared instrumentation program for the purchase of equipment costing in excess of $75,000. Because DRR funds for this purpose were limited to $3.7 million, submission of only one application per qualifying institution was permitted. Despite this restriction, 205 eligible institutions applied for instrument needs totalling $39 million.

On the basis of these recent experiences, it is estimated that the NIH community of scientists, given the opportunity, would demonstrate an overall need of approximately $100 to $150 million for shared research instrumentation. If additional funds were provided, it is estimated that NIH could award $20 million a year for five years in support of shared instrumentation to meet the very highest quality research needs. These needs have been made known in a report submitted to the Congress in February 1982.

The current A21 provisions allow institutions to include depreciation on items of equipment, and interest payments on items of equipment costing less than $25,000, in the calculation of their indirect cost base.

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The CHAIRMAN. But if you could just wait a few minutes, I would appreciate it, while we check to see if Senator Hawkins can get here, and we will move on to our third witness if we can at this point.

Dr. BRANDT. All right. Thank you.

The CHAIRMAN. But we appreciate having all of you here, and we appreciate the work you are doing.

I am especially pleased to welcome here today Dr. Richard Lee, who is dean of the University of Utah College of Medicine. He is representing the Association of American Medical Colleges. Dr. Lee is a home-grown Utahan who has distinguished himself as a hematologist, a researcher, and an excellent administrator.

I am told that serving as dean of a major medical school is somewhat like trying to keep the peace among several warring kingdoms; that is, fiesty department chairmen who are fighting for their fair share of space and resources, so I know that that is not an easy problem for you. I have to say that that sounds a lot like the U.S. Senate, because we are in a similar boat.

Dr. Lee is highly regarded at home and nationally for his skills as both a physician, as an administrator and, of course, as a leader. We are really delighted to have you here, Dr. Lee, and we will look forward to taking your testimony at this time.

STATEMENT OF G. RICHARD LEE, DEAN, UNIVERSITY OF UTAH COLLEGE OF MEDICINE; ON BEHALF OF THE ASSOCIATION OF AMERICAN MEDICAL COLLEGES

Dr. LEE. Thank you very much, Senator, for that very kind introduction.

The Association of American Medical Colleges is pleased to have this opportunity to testify before this committee on this legislation. Its relevance to our organization is obvious since, as you know, the association serves as the national representative for the largest single component of the Nation's biomedical and behavioral research enterprise.

Given the time constraints, I will restrict my remarks to the association's major concerns but would request that our detailed statement be entered into the hearing record.

The CHAIRMAN. Without objection, we will put your complete statement into the record at the conclusion of your oral presentation.

Dr. LEE. Thank you.

The association commends the committee for its timely action to renew the expiring authorities under which must operate the National Cancer Institute, the National Heart, Lung and Blood Institute, the medical library assistance program of the National Library of Medicine, and the National Research Service awards program.

Also commendable is the fact that the committee has resisted the pressure brought by groups deeply committed to intensification of research on specific categories of disease to meet their objectives by the establishment of new national institutes. The AAMC fully supports the goals of many of these groups but concurs with the committee that the solution proposed is wrong.

The association is also pleased to be able to support many other provisions of the bill: First, the termination of the service payback requirement for recipients of the National Research Service award program is welcome. This provision appears to be a reasonable and risk-free solution to the problems presented by the Internal Revenue Service ruling requiring full taxation of these awards.

The association has little expectation that the IRS will reverse its 1977 decision mandating full taxation of the awards. Further, the initial purpose of the payback requirement—to prevent these research training awards from being used purely for clinical training in subspecialty areas—has lost its urgency.

Second, the establishment of an Office on Disease Prevention in the Office of the Assistant Secretary and a requirement that the NIH provide Congress with updates on its activities related to preventive medicine and health promotion seems eminently reasonable. The AAMC views these provisions as much more sensible than other proposals that are less well focused and likely to be less effective.

Third, the requirement to submit an annual report updating activities taken to improve the grant, contracting, accountability, and peer review procedures of the NIH to the responsible committees appears to the association as a useful exercise of congressional oversight as well as a sound solution to a potentially serious problem.

I think I would like to add to these prepared remarks an appreciation of the association for the position you took in introducing the bill on restoration of full coverage of indirect costs. This is a position, I think, that we thank you for, commend you for. The attention to this serious problem is something that I think the academic community welcomes.

The CHAIRMAN. Thank you so much.

Dr. LEE. Now, despite our general concurrence in the provisions of the bill, the association would like to use the bulk of its time to focus on several reservations and problems that we would like to raise for your consideration.

First, in large measure, the stunning success of the NIH can be attributed to effective congressional oversight. That oversight has maintained a balance among many contending forces, including the ambitions of Federal administrators and the importunings of disease-specific advocates. That oversight has recognized the critical importance of flexibility in exploiting scientific opportunity.

The association, as you are well aware, has long opposed time and dollar authorization ceilings for the NCI and the National Heart, Lung and Blood Institute and is firmly persuaded that the national programs for biomedical and behavioral research would best be served by restoring to these organizations the status they enjoyed prior to 1971 and 1972, respectively.

The changes enacted at that time have stimulated progressive fragmentation, balkanization, and loss of flexibility of the NIH, perhaps best seen in the last round of renewals that established detailed statutory specification for the organizational configuration and the program structure of the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases.

The growing tendency to hamstring the national research enterprise in response to special interest pleadings, with earmarks, set-asides, new institutes with detailed prescriptions of organizational structure, minute specification of program content, and so forth, does not harbinger well for future success. The desirability of a return to the status quo ante becomes increasingly apparent.

In this context, the association is delighted that the current proposal is not only virtually free of detailed organizational and program specifications but also takes important steps toward restoring the integrity of the NIH.

Our second concern deals with the authorization ceilings for the NCI, the National Heart, Lung and Blood Institute, the National Research Service awards program, and the Medical Library Assistance program of the National Library of Medicine. These ceilings warrant very careful attention. The flagging Federal support of research and development is becoming more and more of a concern and one that this committee will, we hope, try to address through its jurisdictional role over the NIH.

The latest edition of Science Indicators, published by the National Science Foundation, graphically depicts the decline in U.S. investments in science, particularly nondefense science. Senator John Glenn highlighted this in an editorial recently published in Science magazine, stating the following:

> Research and development support by both government and private sources transformed the United States into the dominant technological force in the world. But our commitment to maintain and extend the amount of research and development necessary to stay ahead in the technological race has slipped. Today, we are witnessing a wholesale retreat in the Federal role in civilian research and development.

In the view of the association, authorizations should be at least high enough to permit appropriations to accommodate inflation. And, should the economy improve, real growth should be resumed. Powerful evidence can be marshaled that indicates enormous private and social rates of return on research investments and supports the argument that economic improvement depends, to a substantial degree, on such investments.

Thus, the arguments advanced for real growth in authorizations, whatever the state of the economy, warrant your earnest consideration. In more specific terms, the authorization ceilings for the Medical Library Assistance and NRSA programs have recently suffered sharp reductions. The extraordinary leadership that the NLM has exhibited in the introduction of new technology for medical information dissemination should not be hobbled by a crippling authorization ceiling.

This concludes my remarks, and I thank you for your attention and would be happy to respond to any of your questions.

[The prepared statement of Dr. Lee follows:]

aamc association of american medical colleges

Testimony of the

Association of American Medical Colleges

on

"The Omnibus Biomedical Research, Research Training, Medical Library Assistance, Health Information and Promotion, and Research Ethics Amendments of 1982"

Mr. Chairman, members of the Committee, the Association of American Medical Colleges (AAMC) is pleased to have this opportunity to testify before this distinguished Committee on this legislation. Its relevance to our organization is obvious since, as you know, the Association serves as the national representative for the largest single component of the Nation's biomedical and behavioral research enterprise. Given the time constraints, I will restrict my remarks to the Association's major concerns but would request that our more detailed statement be entered into the hearing record.

Renewal of Authorities

The Association commends the Committee for its timely action to renew the expiring authorities under which must operate the National Cancer Institute (NCI), the National Heart, Lung and Blood Institute (NHLBI), the medical library assistance program of the National Library of Medicine (NLM) and the National Research Service Awards (NRSA) Programs. Also commendable is the fact that the Committee

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Presented by G. Richard Lee, M.D., Dean of the University of Utah School of Medicine, before the Senate Labor and Human Resources Committee, March 31, 1982.

has resisted the pressure brought by groups deeply committed to intensification of research on specific categories of disease to meet their objectives by the establishment of new National Institutes; the AAMC fully supports the goals of many of these groups but concurs with the Committee that the solution proposed is wrong.

The Association is also pleased to be able to support many other provisions of the bill.

- The termination of the service payback requirement for recipients of the National Research Service Award (NRSA) Program is welcome. This provision appears to be a reasonable and risk-free solution to the problems presented by the Internal Revenue Service (IRS) ruling requiring full taxation of these awards. The Association has little expectation that the IRS will reverse its 1977 decision mandating full taxation of the awards. Further, the initial purpose of the payback requirement---to prevent these research training awards from being used purely for clinical training in subspecialty areas---has lost its urgency.
- The establishment of an Office on Disease Prevention in the Office of the Assistant Secretary and a requirement that the NIH provide the Congress with updates on its activities related to preventive medicine and health promotion seems emminently reasonable. The AAMC views these

provisions as much more sensible than other proposals that are less well focused and likely to be less effective.

- The requirement to submit an annual report updating activities taken to improve the grant, contracting, accountability, and peer review procedures of the NIH to the responsible Committees appears to the Association as a useful exercise of Congressional oversight as well as a sound solution to a potentially serious problem.

Despite general concurrance in the provisions of the bill, the AAMC would like to use the bulk of its time to focus on several reservations and problems that should be raised for your consideration.

- In large measure, the stunning success of the NIH can be attributed to effective Congressional oversight: that has maintained a balance among many contending forces, including the ambitions of Federal administrators and the importunings of disease-specific advocates; and that has recognized the critical importance of flexibility in exploiting scientific opportunity. The Association, as you are well aware, has long opposed time and dollar authorization ceilings for the NCI and the NHLBI, and is firmly persuaded that the national programs for biomedical and behavioral research would be best served by restoring to these organizations the status they enjoyed prior to 1971 and 1972 respectively. The changes enacted at that time have stimulated progressive fragmentation, balkanization and loss of flexibility of the NIH, perhaps best seen in the last round of renewals that established

the detailed statutory specification for the organizational configuration and the program structure of the National Institute of Arthritis, Diabetes and Digestive and Kidney Diseases (NIADDKD). The growing tendency to hamstring the national research enterprise, in response to special interest pleadings, with earmarks, set-asides, new institutes with detailed prescriptions of organizational structure, minute specification of program content, and so forth does not harbinger well for future success. The desirability of a return to the status quo ante becomes increasingly apparent. In this context, the Association is delighted that the current proposal is not only virtually free of detailed organizational or program specifications but also takes important steps towards restoring the integrity of the NIH.

The authorization ceilings for the NCI, the NHLBI, the NRSA program, and the Medical Library Assistance program of the NLM warrant very careful attention. The flagging Federal support of research and development is becoming more and more of a concern and one that this Committee will, we hope, try to address through its jurisdictional role over the NIH. The latest edition of Science Indicators, published by the NSF, graphically depicts the decline in U.S. investments in science, particularly non-defense science. Senator John Glenn highlighted this in an editorial recently published in "Science" magazine, stating: "Research and development support by both government and private sources transformed the United States into the dominant technological force in the world. But our commitment to maintain and extend the

amount of research and development necessary to stay ahead in the technological race has slipped. Today, we are witnessing a wholesale retreat in the federal role in civilian research and development." In the view of the Association, authorizations should be at least high enough to permit appropriations to accommodate inflation. Should the economy improve, real growth should be resumed. Moreover, powerful evidence can be marshalled that indicates enormous private and social rates of return on research investments and supports the argument that economic improvement depends to a substantial degree upon such investments. Thus, the arguments advanced for real growth, whatever the state of the economy, warrant your earnest consideration. In more specific terms, the authorization ceilings for the Medical Library Assistance and NRSA programs have recently suffered sharp reductions. The extraordinary leadership that the NLM has exhibited in the introduction of new technology for medical information dissemination should not be hobbled by a crippling authorization ceiling.

This concludes my remarks. Thank you for your attention. I would be happy to answer any questions you may have.

The CHAIRMAN. Well, I want to thank you for your remarks and for your summary statement.

Dr. Lee, I appreciate the general endorsement of the Association of American Medical Colleges of the reauthorization bill. In your statement, you indicated your organization's approval of the termination of the service payback requirement for recipients of the National Research Service awards. You focused primarily on the taxation of these awards, which undoubtedly presents a burden to trainees trying to maintain a living with those stipends.

Would you care to elaborate on this aspect and clarify other concerns you may have about this payback requirement?

Dr. LEE. Yes. I think this program should be seen primarily as a program which provides an incentive for physicians to engage in biomedical research. Since the establishment of the payback requirements, there has been a situation develop in which a substantially greater portion of biomedical research is done by doctors of philosophy and a smaller proportion by doctors of medicine.

Now, there are many factors in this phenomenon, and the payback requirement is certainly not the only one. But I think that removal of the payback requirement will make it much more attractive for a young physician who, after all, knows that he is already marketable in terms of service delivery—it will make it possible for him to take a chance that he might also be a talented researcher, and if it turns out that, indeed, he fails and he does not have that research talent, he at least is not saddled with a payback requirement.

I think that the way the society as a whole benefits from this is in the attracting of these talented people into the research establishment.

The CHAIRMAN. The emergence of new biotechnologies has done a great deal to promote university and industrial cooperative efforts, particularly in the area of, as I understand it, molecular biology.

Now, in reference to your comments about the wavering of Federal support for biomedical research, do you believe that industrial sources will be capable of taking up some of the funding slack in basic research?

Dr. LEE. Well, there certainly have been a lot of developments in that area that are really quite new to the basic research establishment. I suspect that we will see considerably more support of basic research by industry than we have seen in the past. But I think, although this will look large in relation to past contributions of industry, it will still look rather small in relation to the basic kinds of research support that come from NIH.

I really do not think that we can look to this source to substantially take over what would be a reduced Federal commitment in this area.

The CHAIRMAN. I think what I am going to do is submit some written questions to you as well.

Dr. LEE. Fine.

The CHAIRMAN. I will ask you, on behalf of your organization and, of course, in your own right, to answer them as best you can because we are building a record for this bill.

I have been very appreciative of the witnesses who have testified today in support of this bill. To make a long story short, it is not very easy to work on these health matters in this particular committee because we have a wide disparity of belief and activity on health matters in the committee. But it has been amazing how much we have been able to get together over the last year or so, and we intend to do so even more in the future.

I notice that Senator Hawkins is here. Paula, you want to get the NIH people back, right?

Senator HAWKINS. Go right ahead.

The CHAIRMAN. He is finished.

Senator HAWKINS. All right.

The CHAIRMAN. What we will do is, we will ask the former panel to come and Senator Hawkins will ask her questions. Dr. Lee, I would like to meet you right outside here.

Dr. LEE. Thank you.

Senator HAWKINS. In the alley?

The CHAIRMAN. In the alley, Senator Hawkins says. [Laughter.]

Senator HAWKINS. I apologize for the activities of the Senate today, but I will confess, I am not in charge.

The Committee on Labor and Human Resources is pleased to be holding a hearing on a subject of such interest to the American people and to our health. The committee is aware that the National Institutes of Health is considered, worldwide, to be the strongest institute of its kind. However, we also are aware that many major health discoveries, such as penicillin and interferon, came to this country from overseas sources, as did the CAT scanner, which is revolutionizing diagnosis.

These advances from elsewhere tell us we cannot afford to be complacent about NIH because sometimes we are not always foremost. Of course, the biggest institute within NIH is the National Cancer Institute. Some of the greatest progress made in the last decade came from the exploitation of developments made prior to the 1971 Cancer Act, including the initiation of work leading to remarkable successes with childhood leukemia, but before we in the Congress reauthorize the program, we want to ask some questions.

As everyone knows, we have asked questions, and what we have found is that the NCI is not always sure of the pathways through which experimental drugs are flowing. Certainly this is true when radioactive drugs are sent through the mail without proper labeling, and these potentially death-dealing experimental drugs are not always accounted for.

As for the relationship between the NCI and the Food and Drug Administration, one could say that they are characterized by deeply embedded scorn for the regulatory process and that NCI workers feel their thoughts are behind the comprehension of FDA scientists. While these agencies are wrangling, patients suffer. This is intolerable, and we have not said the last on this subject, but there has been great improvement on the subject.

The existence of program deficiencies was substantiated in a report of a task force appointed by Dr. Brandt to review and evaluate NCI and FDA joint programs. The task force recommended the NCI strengthen its drug development management activities to insure that researchers using investigational drugs comply with

the approved treatment plans, drug distribution policies, and adverse drug reaction reporting procedures.

I certainly was encouraged by the findings and the recommendations of the task force report, Dr. Brandt, and I commend you once again for your good work there. They provided hope, for the first time, that constructive solutions will be found in programs that are vital to us all.

A timetable has been established for implementation of these recommendations, and I remain committed to seeing that they are implemented in a timely fashion and with successful results.

I will also study why some important recommendations made by the National Cancer Advisory Board were never implemented by the NCI staff. Recent progress against cancer and heart disease is commendable. This progress clearly shows the advisability of maintaining, along with a substantially funded basic research investment, categorical disease programs.

The National Heart, Lung and Blood Institute has made contributions to the first substantiated decline of a chronic disease in this century. Hypertension kills fewer people now. Now that most infectious diseases in this country are no longer major health threats, the great cripplers should be our primary research concern.

The National Heart, Lung and Blood Institute has made major efforts since the Congress gave it bureau status. It has worked strenuously to identify the high risk factors in vascular disease, and it has researched effectively how to prevent stroke, and it has produced impressive results in the rehabilitation of stroke victims.

It is my expectation that hearings on the NIH this year will lead us all toward faster progress against those chronic diseases which must be the primary targets of the world's largest biomedical research program.

Dr. Brandt, I will ask these questions of you first. I was impressed with your willingness to correct the problems and deficiencies that were addressed at the oversight hearings, and I hope that the task force recommendations are considered and carried out by the NIH.

How optimistic or pessimistic are you concerning the ability of the NCI to correct these deficiencies through administrative action?

Dr. BRANDT. Oh, I am very optimistic. As a matter of fact, I think, in the analysis of those—as you know, I told you at the time that we would give them 30 days to develop a response as to feasibility, and so forth. As it turns out, many of the recommendations, progress had already been made or even in some instances completed.

Also, since I was last here to report on that to you, we have named a new Director of the Bureau of Drugs, Dr. Meyer, who in fact is well aware of this problem and in fact, although he has only been in the job about 2 weeks, he and Dr. DeVita have already met and begun to—I mean, they knew each other but they have met to begin to make sure that the difficulties between the staff people will not become an issue.

Senator HAWKINS. That is encouraging.

Dr. Brandt, you are nationally recognized not only for your well-known administrative work as vice chancellor for health affairs at the University of Texas but also for your expertise in family practice and community medicine.

Since you have come to Washington, have you had an opportunity to explore the community work of the NCI, and if so, have you found any outstanding work, or have you suggested any departures?

Dr. BRANDT. Actually, to be absolutely honest, I have not looked at it in very great detail, but I am sure that you are aware of the article that appeared in the paper this morning——

Senator HAWKINS. I read it.

Dr. BRANDT [continuing]. From that announcement. I think that you have stimulated me to find out a good bit more about the community program by that question.

Senator HAWKINS. In the National Cancer program's published plan for fiscal years 1980 to 1982, there is a statement that occupational studies of populations exposed to specific occupational carcinogens or suspected carcinogens will be expanded. The emphasis was put on lung cancer, particularly in southern U.S. coastal areas. Could you tell us if this important expansion is taking place?

Dr. BRANDT. I don't know that it has yet begun. I will have to ask Dr. DeVita specifically to address that.

Dr. DEVITA. Yes, we are making plans for a very large case-control study in lung cancer that was recommended by a report that was prepared by Drs. Dole and Pitoe through the OTA and Congress. This is going to be a very substantial endeavor that will try to sort out other factors that are involved in the causation of lung cancer.

Senator HAWKINS. Thank you.

Dr. Brandt, what do you think the family physician or the community physician can do to better serve high risk populations cited by the NCI?

Dr. BRANDT. When do I think that they——

Senator HAWKINS. What do you think the family physician can do to better serve high risk populations?

Dr. BRANDT. Oh, I think they can do a variety of things. In the first place, I think they can be diligent about identifying the early onset of symptoms and the early onset of disease so that intervention can begin at that time.

I think when they have discovered people who are high risk because of certain exposures, they can certainly begin to work with the powers to be in that community and with the people themselves to minimize, limit, or try to eliminate that exposure.

They can also work with them in their health maintenance program for individuals. For example, one of the difficulties that has plagued many of the studies of the environment and its role in pulmonary disease has been the whole issue of smoking, because we know very well that if you are exposed to asbestos, a known carcinogen, pulmonary carcinogen, at least, that your chance of developing cancer is almost ninetyfold greater if you smoke.

So the question is, if someone works in those kinds of environments and smokes, whence cometh the cancer? That is part of the problem that we have. I think that, therefore, family physicians as

educators of their patients can certainly play a significant role in trying to keep them informed and help them lower their risk.

Senator HAWKINS. Thank you. I have some other questions for you, and I would like to submit them in writing and ask for a response for the entire committee to review.

Dr. BRANDT. Fine.

Senator HAWKINS. We have a vote on, but I have a couple of questions for Dr. DeVita. I also have questions for Dr. Frommer which I will submit for the record.

Dr. DeVita, you mentioned at a recent cancer board meeting that your institute had started more new programs under your leadership, in a time when the budget was rather stable, than at any other earlier time in its history, and I would like to compliment you on that. Could you tell me what those new programs are?

Dr. DEVITA. Yes, Senator Hawkins. I think there are some very exciting ones in the sense that the cancer program, over the past decade, has developed a lot of information on the relationship of the environment to the causation of cancer, particularly diet and micronutrients and macronutrients. We did not have an effector on, a way of applying these before, and we have developed a new chemo prevention program which promises to reduce the instance of some of the more common forms of cancer.

We have developed a radiation research program which we have submitted to the Department for approval. We have developed a biologic response modifier program which is taking advantage of the newly described biologicals for treating cancer, interferon being one, and we have recently developed what we call a cancer control research unit. These will seek studies in defined population areas so that we can set some national goals for reducing mortality within defined populations as we apply some of these.

And, of course, there is the community clinical oncology program that you are familiar with, that we discussed at your first hearing some months ago, all of which are not inexpensive and have required reprograming of dollars from other programs in order to let them get started. So those are some of them.

We have a new program we are just starting in the next several months called the PDQ, a patient data query system, which we hope to develop, an interactive computerized system that patients and doctors will be able to deal with to lead them in the direction of the most appropriate management of their cancer.

Senator HAWKINS. If you think of any others, if you would submit them, I would be perfectly happy to receive them.

Dr. DEVITA. Sure.

Senator HAWKINS. The committee had been told that you reviewed each and every NCI contract shortly after you became the Acting Director, and the implication was that you curtailed or eliminated about 35 to 50 million dollars' worth of contractual work.

How much do you believe was eliminated, and how did you reallocate that money?

Dr. DEVITA. Well, what we did was, there were some programs that were developing resources for researchers; that is, viral products that could be used by laboratory researchers. The technology had changed a great deal and did not require such bulk resources.

We were able to reduce some of those contracts by about $10 million.

We reprogramed most of the money into our grant pools, and we have been able to fund our grants at the level equivalent to the other institutes at the NIH when our increases were somewhat lower. Most of the money has gone into our research project pool.

Many of these programs had served their purpose very well in the past, but times had changed, and we just turned the money over to something else.

Senator HAWKINS. I have about three pages of questions for you, I will submit the remaining questions for you to answer, since we have the 5-minute vote on.

At this point I order printed all statements of those who could not attend and other pertinent material submitted for the record.

[The material referred to follows:]

Testimony of

Mrs. Jean Schneider
President

JUVENILE DIABETES FOUNDATION

regarding

S. 2311, "The Biomedical Research, Training, and Medical Library Assistance Amendments of 1982"

before the

Senate Committee on Labor and Human Resources
Sentor Orrin Hatch, Chairman

March 31, 1982

Senator Hatch and members of the Committee:

I am Lee Ducat, Founder and First President of the Juvenile Diabetes Foundation. I have served on the National Diabetes Advisory Board since its inception. I am the mother of a 26 year old diabetic son.

Need for a National Institute of Diabetes, Endocrinology, and Metabolic Diseases.

Almost nine years ago, I testified before this Committee on the need to create a National Commission on Diabetes. I said: "The picture is bleak for the diabetic. He must live dependent on an insulin bottle, syringe, and alcohol swab for life. He faces a grab bag full of dreadful complications and a shortened life expectancy. There has been no change in 50 years since the discovery of insulin. The public, Congress, and the NIH are generally unaware of the real problems of diabetes."

This Committee and the Congress responded because NIH and what was then known as NIAMDD would not recognize diabetes:

Congress created the National Commission on Diabetes.

Congress created the National Diabetes Advisory Board in legislation which you co-sponsored.

Congress created the Diabetes Research and Training Centers.

Congress insisted that the various associate directors be appointed within NIAMDD.

Congress -- this Committee -- extended the life of the NDAB over NIH objections.

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Congress appropriated more and more dollars to diabetes research and literally forced NIH and NIAMDD -- through earmarking, report language, and the like -- to develop a comprehensive diabetes plan.

Congress brought diabetes into the 20th century. There is now great hope for the diabetic young and unborn. The research advances -- the insulin pump; isolation of a virus; transplantation; development of pure human insulin; identification of genetic markers -- are a tribute to you and to Congress. All of this has occurred because of your recognition of diabetes as a major national health problem.

We believe that the diabetes initiative will be enhanced by the creation of a National Institute of Diabetes, Endocrinology, and Metabolic Diseases. Legislation will be introduced in the Senate shortly to accomplish this objective. And that is why we have come to this Committee once again.

The impact of diabetes -- in human, social, and economic terms -- demands a renewed, invigorated Federal commitment. A modest increase in funding, coupled with the augmented visibility an institute would provide, would embody virtually all of the elements necessary to maintain our momentum towards a cure.

Over the past decade, NIADDK has become a patchwork polyglot of hundreds of unrelated diseases and disorders. Quite

simply, there is no logical reason for this institute's structure. It has served as the dumping ground for every categorical disease lacking a home. The composition of this Institute guarantees inequity and inefficiency in the administration of important health research programs.

The fact that Congress has identified the need to establish so many Commissions, Advisory Boards, Coordinating Committees, and Advisory Council Subcommittees -- is indicative of the irrationality of the grouping of NIADDK programs and the dissatisfaction of countless constituent groups with the current structure of the Institute.

We support Dr. Lester Salans, Acting Director of NIADDK. He is an energetic, aggressive, innovative leader who can boast great responsibility for the strides the Federal diabetes program has made and who has done the best job possible to administer the endless disease programs which demand attention. However, regardless of exemplary leadership, the structure of this entity alone will impede progress in combatting all the diseases which are part of NIADDK's mandate.

NIH is viewed throughout the world as the premier biomedical research center. But this does not mean that its operations cannot be improved. This Committee should amend NIH's authorities if it will facilitate greater, faster progress in combatting diseases. For those of us with diabetic children, an extra year before a cure could mean the onset of blindness or neuropathy. Your proposed legislation, Senator Hatch, extends

NIH authorities for three more years. We are afraid to wait for three years or for a "better climate on Capitol Hill" to do what must be done.

We are not proposing the establishment of a new bureaucracy with significant administrative, overhead, and personnel costs. We are proposing to simply take the current DEM cluster out of NIADDK and plant it within NIH as a new institute. There are no new substantive programs proposed, and overall funding authorization levels, i.e., Diabetes Research and Training Centers, could actually be reduced below current authorization levels.

Senator Hatch, we are asking for a National Institute of Diabetes, Endocrinology and Metabolic Diseases because we are so close to a cure for diabetes and its complications. The DEM effort must be streamlined. In your support of prior diabetes legislation, you set an example for the whole world to follow. Your investment has yielded huge dividends for our children. We are prayerful that you will continue to be courageous and forceful in taking the next step -- the creation of a National Institute of Diabetes, Endocrinology and Metabolic Diseases -- to rid our society of these dreaded diseases.

We respectfully recommend that the creation of such an Institute be incorporated within S. 2311.

Extension of the Legal Operating Authorities of the National Heart, Lung and Blood Institute.

Among the most important provisions of S. 2311 are those which provide the extension of the legal operating authorities of the National Heart, Lung, and Blood Institute. We offer our enthusiastic support for this Institute and applaud you for providing for a three-year authorization of its programs.

As mentioned above, diabetes is a polyglot of a disease. It spans the body systems and hence, spans the Institutes of NIH. Diabetes research is supported in ten of the eleven National Institutes of Health. But in no Institute has there been a more conscientious, agressive and innovative campaign against diabetes than that waged by the National Heart, Lung and Blood Institute and this comprehensive research and training effort has been spearheaded by two of the biomedical research community's most dedicated leaders, Acting NHLBI Director Dr. Peter Fromer and the former Director of the Institute, Dr. Rober Levy.

Why is the work of this Institute so important to me? Because I, like millions of parents of diabetics, live with the fear that my child will be stricken down by heart disease related to his diabetes in the prime of his life -- just as it stuck down your friend and ours, Congressman William Stiger. Diabetes is one of the four major risks of cardiovascular disease in the United States. The diabetic is twice as prone to coronary heart disease than the non-diabetic, twice as susceptible to stroke, five times as likely to develop arterial diseases of the limbs.

JDF applauds you, Senator Hatch, for providing a three-year extension of its programs; as you know, the one- and two-year extension of this past decade have not contributed to the stability and continuity of NHLBI's programs.

We would recommend, however, that your legislation be amended to provide for authorization of "such sums as may be necessary" for NHLBI's Research and Prevention, Education, and Control programs. This would render NHLBI's authorities consistent with the remainder of NIH.

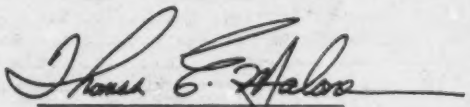
We sincerely hope that your Committee will favorably consider our proposed recommendations.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health

REPORT ON SHORTAGES IN RESEARCH EQUIPMENT AND INSTRUMENTATION



Thomas E. Malone, Ph.D.
Acting Director, NIH

February 1982

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

National Institutes of Health

REPORT ON
SHORTAGES IN RESEARCH EQUIPMENT AND INSTRUMENTATION

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REPORT ON SHORTAGES IN RESEARCH EQUIPMENT AND INSTRUMENTATION

Executive Summary

In Senate Report No. 97-268, the Committee on Appropriations requested that the NIH conduct a study on the magnitude of the problem of shortages in research equipment and instrumentation in the biomedical research community and report back to the Committee its findings including estimates of the total funding required to remedy the situation, how such funds would be administered, and the criteria for their allocation. The following is submitted in response to that request. The budget estimates included represent the professional judgment of NIH staff and do not reflect actual future budget recommendations.

Extensive studies of the obsolence and shortage of biomedical research equipment and instrumentation over the past decade have confirmed that a growing problem exists in regard to (1) the actual supply of state-of-the-art equipment and the access of investigators to it, and (2) the development of instrumentation to utilize new technologies required for furthering advances in biomedical research.

The NIH research project system provides reasonably well for relatively inexpensive equipment which does not lend itself to shared usage. State-of-the-art instrumentation costing in excess of $30,000, which can be used by a group of investigators, is provided for NIH grantees, of whom at least half must be grantees of the National Institute of General Medical Sciences (NIGMS), through a shared instrumentation program specifically designed to support the needs of research projects in the areas of interest to NIGMS. The Division of Research Resources (DRR) also provides for shared instrumentation through institutional awards to qualified grantees. Based on recent program experience, it is estimated that approximately $20 million a year for five years is required by NIH to replenish and maintain the adequacy of the nation's biomedical research community's needs for medium-priced shared instrumentation.

The mission of the Biotechnology Research Program (BRP) of DRR is to assure the development and availability of high technology instruments that apply concepts and techniques from the physical sciences, mathematics, engineering, and computer science to biomedical research. To establish and renew state-of-the-art instrumentation so costly as to mandate sharing on a regional or national basis, it is estimated that the BRP requires additional $5 million increments each year for the next five years.

The equipment and instrumentation issues described above apply to biomedical research broadly, but some equipment and instrument needs are categorical in nature and call for solutions that differ from those that respond to multicategorical needs. High technology instrument development such as that being supported by BRP requires specific fostering and combined sources of support when instrument need is categorical. A pilot series of cofunded program project grants, now being considered by NIH, should demonstrate the efficacy of this approach by promoting instrument conceptualization, prototype design, and construction, all of which serve to advance categorical research.

REPORT OF SHORTAGES IN RESEARCH EQUIPMENT AND INSTRUMENTATION

INTRODUCTION

In its report on the fiscal year 1982 budget for the Department of Health and Human Services, the Committee on Appropriations stated:

> "The Committee has viewed with concern the growing problem of obsolescence and shortages in research equipment and instrumentation in the biomedical research community. In the interests of maintaining the quality and efficiency of research, the Committee urges that the Office of the Director of NIH conduct a study of the magnitude of the problem and report back to the Committee, no later than January 15, 1982, its findings including estimates of total funding required to remedy the condition, how such funds would be administered, the criteria for allocating funds and the amounts recommended for fiscal year 1982." (Senate Report No. 97-268, page 49)

The following report has been prepared by the National Institutes of Health of the Department of Health and Human Services in response to this request.

BACKGROUND

During the 1960's the Federal government's support of biomedical research and development in the nation's universities fueled an unprecedented biological revolution. Research instrumentation provided an indispensable contribution to the scientists' elucidation of life processes in health and disease and the resultant new means to prevent, treat, and cure human ills. Evidence is growing steadily, however, that there is a shortage of modern equipment in laboratories conducting federally-supported biomedical research. Today there is general agreement among investigators, research administrators, and officials of research funding agencies that the problem is significant.

Ten years ago the National Academy of Sciences conducted a survey of research equipment needs in a sample of large, medium, and small academic institutions. Teams of scientists were sent to examine existing resources firsthand, to interview investigators to learn what equipment was needed, and to assess the validity of the need. The survey permitted extrapolation of the findings to an estimate of the need in all academic institutions. The report, Survey of Research Equipment Needs in Ten Academic Disciplines, published in 1972, presents equipment needs for each discipline by the cost of the equipment. 1/

Smith and Karlesky, in their 1977 State of Academic Science, reported findings of major deficiencies in sophisticated instruments required for basic research in colleges and universities. 2/ In May 1980 the National

Commission on Research published a report which described the difficulties in developing and maintaining large research facilities and the problems of instrument obsolescence in the nation's research universities. 3/ Just one month later the results of a study conducted by the Association of American Universities, The Scientific Instrumentation Needs of Research Universities, were released. 4/ Most recently, in addressing a federal interagency committee that was convened by the National Science Foundation at the request of the Office of Science and Technology Policy, Dr. Keyworth characterized the research instrumentation situation in this country's universities as a "disgrace."

The cumulative and mutually reinforcing recommendations of these studies can be summarized as follows:

- The research universities, which are responsible for conducting a critical share of the nation's basic biomedical research and training, are facing serious financial difficulties in replacing worn out and obsolete equipment and in purchasing and/or developing the new instrumentation required for further research advances and state-of-the-art research training.

- During the past decade, as the competition for research funds grew ever more intense, universities made the support of the investigators and supporting staff their first priority (i.e., salaries and associated personnel expenditures). As a result of this effort to continue support for researchers, universities have been forced to further reduce expenditures for instrumentation.

- The equipment being used in the top-ranked university laboratories receiving Federal research and development funding has a median age twice that of equipment in leading industrial laboratories. Because these universities are responsible for training future investigators for science and industry, deficiencies in research equipment bode ill for future research in all settings.

- Because OMB Circular A-21 excludes depreciation on equipment purchased with Federal funds as an allowable indirect cost, a potentially important option for obtaining replacement funds is not available.

- In an age when biological research is becoming increasingly sophisticated and instrument-dependent, the Nation is rapidly losing its competitive position in biomedical research as European and Japanese laboratories expand their scope and increase their pace.

DISCUSSIONS AND RECOMMENDATIONS

The conclusions summarized above were based almost entirely on analyses of historical trends and interviews with educators, administrators, and scientists. The conclusions drawn are qualitatively sound, but more quantitative data should be sought. In the meantime, relief must be provided to remedy clearly identified problems.

The two major problems of obsolescence and shortage in research equipment for biomedical research are as follows: one is to provide investigators with access to state-of-the-art instruments; the other is to develop instruments to respond to needs for new capability and to take advantage of new technology. The projections of opportunity which follow are based, not only on perceived need, but also on what it is believed the scientific community is prepared to exploit. Each of the following budget estimates represents the professional judgment of NIH staff, and does not reflect actual future budget recommendations.

State-of-the-Art Instrumentation for Individual Laboratories

The investigator-initiated research proposal is the mainstay of the NIH extramural research program. Stabilization of this portion of the NIH activity has been given precedence over all other extramural funding obligations. In FY 1980 these awards accounted for a total of about $1.8 billion. Funding for small-scale (usually under $20,000) instrumentation required to do the work proposed, when it is not otherwise available, is provided by the award. Ultracentrifuges, refrigerated centrifuges, scintillation counters, amino acid analyzers, cell counters, infrared and ultraviolet spectrometers, x-ray diffraction equipment, and automatic sample collectors are examples of sophisticated items of equipment which do not normally lend themselves to shared usage that are funded through the research project system.

A recent study by Vener 5/ of research project grants shows that 76 percent of the sums awarded in the equipment category in FY 1979 were for less than $10,000. Almost half of the amounts awarded for equipment was in the range of $300 to $9,999. Furthermore, in a detailed study of 462 applications reviewed by 37 study sections, there was no single initial review group which appeared to systematically reduce equipment requests without scientific justification. Nor was there any systematic Institute staff reduction of the original equipment request. It is felt, therefore, that the system provides reasonably well for most instrumentation needs at the research project level.

State-of-the-Art Instrumentation Shared on an Institutional Basis

Some instrumentation can be purchased and installed for use by more than one investigator where the research need is important but intermittent, e.g., computer equipment, electron microscopes, and mass spectrometers. Decisions to select and purchase this equipment can often be made best at the local level. The Biomedical Research Support Grant (BRSG) program of the Division of Research Resource (DRR), which provides institutions with support of activities to enhance the research environment, is one mechanism which fills this need. The award is based on a formula which takes into account the institution's level of NIH research support; in this formula, the purchase of shared instrumentation is an approved activity.

However, because of the many important uses for BRSG funds and the modest size of the awards, these grants support relatively little in the purchase of major instruments for shared use. In view of this the BRSG Program initiated in 1982 a separate competitive shared instrument grant program which is described below.

Recognizing the increasing need for instrumentation, the National Institute of General Medical Sciences (NIGMS) announced in FY 1979 a shared research instrumentation program for NIH grantees, of whom at least half were required to be NIGMS grantees. Each award funded the purchase of instruments or instrument clusters with a capital cost greater than $40,000. The maximum award was limited to $150,000, included in which was $15,000 per year for a period of three years for operating and maintenance costs. Proposals requesting $26 million were received. Available funds allowed a total of approximately $9.0 million of awards to be made in FY 1979 and FY 1980. The program was reannounced in FY 1981 for instruments with a capital cost greater than $30,000 and a limit of $200,000 per award. All other features were the same. Proposals requesting $28 million were received in response to the reannouncement of the ongoing program.

In an effort to meet the needs of others in the NIH research community, DRR announced a shared instrumentation program for the purchase of equipment costing in excess of $75,000. Because DRR funds for this purpose were limited to $3.7 million, submission of only one application per qualifying institution was permitted. Despite this restriction, 205 eligible institutions applied for instrument needs totalling $39 million.

On the basis of these two recent experiences, it is estimated that the NIH community of scientists, given the opportunity, would demonstrate an overall need of approximately $100 to $150 million for shared research instrumentation. If additional funds were provided, it is estimated that NIH could award $20 million a year for five years in support of shared instrumentation to meet the very highest quality research needs.

State-of-the-Art Instrumentation Shared on a Regional or National Basis

The Biotechnology Resources Program (BRP) of the DRR, operating successfully since 1962, has demonstrated the validity of the concept of shared regional instrumentation resources. The BRP concentrates on the application of the physical sciences, mathematics, and engineering to biology and medicine. Ultrasophisticated instruments, the latest state-of-the-art methods, and expert support personnel provided by the program in installations open to many users help life scientists in their efforts to decipher fundamental biological processes or combat human illness. The program's capabilities include large-scale and minicomputer systems; biochemical and biophysical analytical instruments (mass spectrometers, nuclear magnetic resonance

spectrometers, electron spin resonance spectrometers); million-volt electron microscopes; electron microprobes; biomedical engineering technologies; and production of biochemical research materials. These capabilities are made available as resources which must be shared among a number of investigators on a national or regional level. Technological capabilities are provided in this way to overcome restraints of high cost, complexity, or scarcity affecting availability and uses of equipment required to achieve scientific progress. An NIH publication, Biotechnology Resources, 6/ describes the research resources supported by the BRP in 1981.

In order for the U.S. to maintain its preeminence in biomedical research, it must foster creativity in biotechnology and instrument development. There exist many laboratories with exceptionally talented individuals in specific areas of science, e.g., simulation systems, chemical sensor development, large scale integrated circuit design, and the use of time shared computer systems; the problem is to put this expertise to work on biologically and medically important problems. A series of workshops on Technology in Support of Biomedical Research, held at the Johns Hopkins School of Medicine in August 1981, have reaffirmed the latent capacity of the biomedical research community to expedite the transfer of concepts and techniques from the physical, mathematical and engineering sciences to applications in biology and medicine.

Continued prospects of significant fiscal restraints require that the extension of the BRP be achieved through the judicious selection and placement of resources believed to be the most promising for fostering new advances in science. It is professional judgment of the BRP staff that a modest expansion of its program by an estimated $5 million per year for the next five years is required to assure the development and availability of high technology instruments for biomedical research.

The NIH is also exploring the possibility of capitalizing on the potential to apply advanced technology in the development of new instruments for categorical research through cofunded program project grants. Joint review of each application and cofunding of each grant by DRR and the appropriate Institute would ensure that both the technical and applied facets of the proposed research could be accurately assessed and developed. For example, funding for the instrumentation core might be assumed by DRR while the Institute might support the application of the technology.

The NIH is considering a national conference in 1982 to identify the most exciting instrument modalities and configuration and to establish the criteria for their placement, management, and operation toward increasing self-sufficiency. Of necessity, this will include consideration of the most efficacious means of funding i.e., grant, contract or cooperative agreement--and the value of promoting cost sharing with industry and other federal agencies.

In addition, the NIH is considering the establishment of an NIH-wide National Biomedical Research Resources Program (NBRRP) to coordinate the development of program plans and budget strategies for the economical support of research

resources. Traditionally, virtually every component of the NIH has been involved in some way in the support of research instrumentation. And, to-date, loose coordination has been sufficient. However, in the light of an evermore stringent budget, the envisioned NBRRP may be the best means to address policies and priorities related to initiating, maintaining, or where necessary, eliminating, instrumentation programs to ensure that as many of the NIH interests as possible will be optimally served.

References

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4. The Scientific Instrumentation Needs of Research Universities. A report to the National Science Foundation by the Association of American Universities, June 1980.

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GOVERNMENT INDUCEMENTS FOR PURCHASE OF RESEARCH EQUIPMENT

*Universities:

Indirect cost allowance

1. HHS permits a 6⅔% of acquisition cost use allowance on equipment not purchased with federal funds in calculating the indirect costs for research. This assumes a 15 year life period of equipment.

Industry:

The 1981 Tax Law for Accelerated Cost Recovery System

1. For non R&D equipment a five year life period of equipment is assumed for tax deductions. For equipment purchased during 1981-84 the following tax deductions are permitted:

	1st	2nd	3rd	4th	5th year
	15%	22%	21%	21%	21%
During 1985	18%	33%	25%	16%	8%
During 1986 and after	20%	32%	24%	16%	8%

In addition a 10% tax credit may be applied during the five year period.

2. For R&D equipment, a three year life period of equipment is assumed for tax deductions. For equipment purchased during 1981-84 the following tax deductions are permitted:

	1st	2nd	3rd
	25%	38%	37%
During 1985	29%	47%	24%
During 1986 and after	33%	45%	22%

In addition, a 6% tax credit may be applied during the three year period.

IT TURNS OUT THAT THE FIVE YEAR PERIOD IS MOST BENEFICIAL TO INDUSTRY CONSIDERING THE TAX CREDITS

Manufacturers of equipment for the physical and biological sciences may receive a tax deduction on equipment donated to universities. The deduction is equal to the cost of the equipment plus ½ of the difference between the market and production costs. Industry in general may donate equipment on a "charity" basis and receive a deduction of the cost of the equipment. This cannot exceed 10% of their total deductions

*Universities do have access to a variety of funding agencies for the purchase of equipment.

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AMERICAN COLLEGE OF CARDIOLOGY

STATEMENT

of

Suzanne B. Knoebel, M.D., F.A.C.C.
President-Elect

on

S. 2311 - "Omnibus Biomedical Research, Research Training, Medical Library Assistance, Health Information and Promotion, and Research Ethics Amendments of 1982"

to

Labor and Human Resources Committee
United States Senate
Honorable Orrin G. Hatch, Chairman

April 15, 1982

Mr. Chairman and Members of the Committee:

I am Dr. Suzanne B. Knoebel, Herman C. and Ellnora D. Krannert Professor of Medicine at Indiana University School of Medicine. I represent the 11,500 member American College of Cardiology of which I am currently President-Elect. We appreciate the opportunity to comment on various provisions of S. 2311, "Omnibus Biomedical Research, Research Training, Medical Library Assistance, Health Information and Promotion, and Research Ethics Amendments of 1982", with particular relevance to the National Heart, Lung, and Blood Institute (NHLBI).

The American College of Cardiology is of the opinion that the performance of the NHLBI has been exemplary under the current statutory authority; and, it is probable that the Institute would continue to perform admirably if the authority were merely extended without amendment, provided sufficient funds were available to allow the Institute to address the many vital issues falling under its broad responsibility. We commend you for recognizing that the statute needs little revision. However, the College believes that as its members have special expertise in the biomedical research process and a vested interest in quality health care, we also have an obligation to direct your attention to those aspects of the proposed legislation and current statute which we believe might be enhanced in effectiveness through amendment and those with which we are in full agreement as proposed. The primary areas of concern which are addressed are:

The American College of Cardiology (ACC), a nonprofit professional medical society and teaching institution, is dedicated to ensuring optimal care for persons with cardiovascular disease or those with the potential for developing cardiovascular disease and through education and socioeconomic activities, the prevention of cardiovascular disease.

1. Authorizations of Appropriations;
2. Training Programs;
3. Certain Advisory Council Matters;
4. National Research and Demonstration Centers;
5. The National Library of Medicine;

Authorizations of Appropriations

The authorizations for appropriations for each fiscal year is one issue for which we recommend amendment. As the responsibility of the NHLBI is broad with four of the ten leading causes of death falling under its jurisdiction (diseases of the heart (#1), cerebrovascular diseases (#3), chronic obstructive lung disease (#6), and atherosclerosis (#9), it is vital that funding be adequate, stable, non-regressive and flexible.

The NHLBI has a demonstrated record of responsible research management. In terms of accomplishments, the productivity of the NHLBI basic and clinical research projects, demonstration, prevention and education programs toward the amelioration of the severe consequences of heart, lung and blood disorders has been outstanding. As you have heard in previous testimony, the decline in deaths from heart attack and stroke in the United States, a decline which began in the late 1960s, continued through 1981. The many reasons for this decline all have their genesis in a sustaining Federal commitment to research coupled with creative and careful planning and priority setting under the auspices of the NHLBI.

The American College of Cardiology believes that for optimal operation of the Institute and in the interest of nurturing the research productivity and momentum which has been gained over the past decade or two, extension of the authorizations for

appropriations for each fiscal year for the National Heart, Lung, and Blood Institute should be granted on the basis of scientific need and opportunity. Specification of absolute dollar levels has an inherently negative impact as dollar limits operate as restrictive ceilings rather than opportunity levels. For example, in the past few years, authorization levels have only minimally exceeded appropriations and we believe this has been inhibitory to research creativity as new initiatives could not be seriously considered or planned for. Consequently, the College would recommend that authorizations be for "such sums as may be necessary". It must be made clear that we are not recommending a carte blanche for profligate spending as annual appropriations will require justification as usual. It is simply to allow creative research management and the ability to take advantage of unexpected opportunities should they arise.

If acceptance of the above language is not possible, the alternative is to develop authorization levels sufficiently high to permit responsible planning for new initiatives and opportunity exploitation. Our recommendations for such authorization levels are:

$ 706,000,000 for FY 1983;

$ 777,000,000 for FY 1984;

$ 855,000,000 for FY 1985;

$ 941,000,000 for FY 1986; and

$1,035,000,000 for FY 1987.

We further believe that authorization levels for prevention, education, and control activities, exclusive of training, should be integrated into the overall NHBLI authorization levels. These

activities are an essential component of most NHLBI activities and to maintain a separate authorization for specific activities serves only to obscure their importance relative to the entire NHLBI effort.

In addition, because the College believes that the Institute has functioned well and will continue to function well as monitored by Congress, and because stability is of the most important concern to the productivity of the research enterprise, we endorse a five year reauthorization.

In addition, the College believes it to be essential for Section 301 authority to be maintained for NHLBI in order to provide appropriate flexibility to the Institute for areas of unexpected research promise and need, as has occurred historically.

Research Training

While dollars for research training programs of the NHLBI are not specifically identifiable within S. 2311, we do wish to make comment on the importance of this aspect of the reauthorization process and recommend some clarifications and modifications. A critical problem faced by the NIH, in general, and NHLBI, in particular, is the dramatic decline of physicians entering careers in academic investigative medicine. If this downward trend is permitted to continue, clinical investigation may become an historical pursuit and our large investment in biomedical research devalued to an irreversible level. The ultimate relevance of any research advance must be related to its significance for the human with disease or the potential for developing a disease process. Unless there is a consistent

approach to training funding which recognizes the absolute necessity for an adequate cadre of clinical investigators, our research productivity and relevance will be continually compromised.

In view of the critical role of training in the entire research and research translation process, the College recommends that authorization levels of $231 million, $255 million, $270 million, $297 million and $327 million for Fiscal Years 1983-1987, respectively, be ensured under the NRSA section to allow for adequate training needs of the NHLBI.

Consonant with our concern for encouraging clinical investigation as a career, the College favors repeal of the "payback" requirement under the National Research Service Award program, because we believe it unnecessarily inhibits a young, potential, clinical investigator from embarking on a research career. Concern that such awards would be used for subspecialty clinical training, a concern which prompted the payback requirement, has not shown to be a serious problem. Certainly the drastic decline in clinical investigators is a more pressing societal issue. We are pleased your bill addressed this issue.

Advisory Councils

Membership

S. 2311 continues the National Heart, Lung, and Blood Advisory Council in its current form. We believe the unique needs of the National Heart, Lung, and Blood Institue require it to be separately authorized, but believe certain revisions are appropriate. The current law requires that: (1) eleven members shall be from among leading medical and scientific authorities skilled in the sciences relating to the mission

of NHLBI, (2) two members shall be residents, and (3) five shall be public members who are leaders in the fields of fundamental science, medical science or public affairs. Due to the significantly increased mandate of the NHLBI since 1972, with the addition of lung and blood responsibilities to the National Heart Institute, it has become difficult to achieve an adequate complement of medical and scientific persons within the statutory ceiling of eleven members. Consequently, our recommendation would be to phase out the specific requirement for the two resident positions and thereby increase the number of medical and scientific authorities by two. This recommendation is not to be interpreted as denigrating the contributions of the residents, but, rather, is made in the belief that the purposes of the Council can be better achieved with two additional medical/scientific members on the Advisory Council.

Chairmanship

The College strongly believes that the Chairman of the National Heart, Lung, and Blood Advisory Council should be the Director of the Institute. The College believes that the directors of individual research institutes are the most appropriate chairmen. We urge the Committee to retain the language of Section 417(d) of the current law.

National Research and Demonstration Centers (NRDCs)

Section 415 of the Public Health Service Act contains for National Research and Demonstration Centers for heart, blood vessel, lung, and blood diseases and resources. Section 415

authorizes ten centers each in the three traditional areas of responsibilities of the NHLBI. The College believes that the specific designation of ten centers each for these three areas (heart, lung and blood) should be amended to authorize thirty centers overall. The amendment is recommended to provide the Director of NHLBI more flexibility in the development of new centers, funds permitting, consistent with the needs, availability and equality of ongoing research in the various subject areas under the aegis of the NHLBI. In addition, the current and proposed statutory provisions in terms of numbers of centers (10-10-10) are inconsistent with current funding percentages of the research programs of the Institute which approximate 66%, 17% and 17% for heart, lung, and blood areas, respectively.

National Library of Medicine

The Medical Library Assistance Program provides support for the study, design, development and improvement of information services for health care professionals throughout the nation, and supports a regional library network. We believe that this program must be stabilized and adequately authorized so that sufficient funding can be provided. Because of the pressing needs for this program, the College recommends that the authorization levels for Fiscal Years 1983-87 be increased to $9 million, $10 million, $11 million, $12.2 million and $13.5 million, respectively.

The American College of Cardiology hopes that our concerns, comments and recommendations will be of assistance as you develop this important reauthorization legislation. On behalf of the members of the College, I appreciate the opportunity you have provided us to present our views.

Medical Library Association, Inc.

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April 21, 1982

David Sundwalt, M.D.
Professional Staff
Senate Labor & Human Resources Committees
4230 Dirksen Senate Office Bldg.
Washington, DC 20510

Dear Dr. Sundwalt:

Enclosed is written testimony to be included in the hearings record for S.2311, the "Biomedical Research, Training, and Medical Library Assistance Amendments of 1982." Mr. Grossman indicated that the hearings record would be open through April 23 to accommodate receipt of this information. This testimony has been endorsed by the Executive Committee of the Medical Libary Association and is, therefore, the official position of the Association concerning this bill. The Medical Library Association is a professional organization of approximately 5,000 individuals and institutions in the health sciences library field. Its major purpose is to foster medical and allied scientific libraries, to promote the educational and professional growth of health sciences libraries, and to exchange medical literature among its members.

The Medical Library Association is particularly pleased that S.2311 contains no language relating to the issue of full cost recovery for the National Library of Medicine's information products and services.

Your inclusion of this testimony in the hearings record is very much appreciated. Please notify me if you have questions or would like additional information.

Sincerely yours,

Raymond A. Palmer/cc

Raymond A. Palmer
Executive Director

RAP/cc

Encl.

cc: Lucile S. Stark

Statement of the Medical Library Association
on
Reauthorization of the Medical Library Assistance Act

The Medical Library Association strongly supports a three-year renewal of the Medical Library Assistance Act (MLAA) for fiscal years (FY) 1983-85. It endorses all six programs supported by the Act and calls for increased funding for the Regional Medical Library Program and for resource, research, and training grants; recommended funding levels are $10,11, and 12 million for FY 1983, 1984, and 1985, respectively.

BACKGROUND

The Medical Library Assistance Act of 1965 (P.L. 89-291) was signed into law on October 22, 1965. Congress has subsequently extended this legislation six times, with its most recent extension due to expire on September 30, 1982. The programs of the MLAA are designed to improve health information services by providing funds to strengthen library resources, support the nation's Regional Medical Library network, train professional personnel, conduct research into ways of improving health communication and information transfer, and produce critical reviews and publications on important health topics.

Although minor revisions have been made in the legislation, such as a procedural change for Board of Regents' appointments, the only program area which has been deleted during the Act's 17-year history has been the authority for construction grants. The flexibility of the MLAA has allowed for program changes without major modification of the legislative language.

FUNDING LEVEL

The "Biomedical Research, Training, and Medical Library Assistance Amendments of 1982" proposes a funding level of $8, $8.5, and $9 million annually for FY 1983-85. The Medical Library Association finds these recommended funding levels to be unacceptable. The Association is aware that the reauthorization funding level should closely reflect the appropriations level. The $7.5 million funding for FY 1982 represents a 23% reduction from the FY 1981 budget of $9.8 million. $8 million for FY 1983 represents 18% less than the funding level for FY 1981.

The Medical Library Association's request for reauthorization of the MLAA at funding levels of $10, 11, and 12 million for FY 1983-1985 is not an insensitive response to the current economic plight, but rather the result of careful deliberation with full realization that the proposed funding level represents substantial sacrifice by the medical library community as its contribution to the national effort to strengthen the economy and especially to lower inflation.

Medical librarians are acutely aware of the devastating effect of the rise in inflation. Between 1969-1979 the costs of books and periodicals rose at the rate of 273% and 398% respectively. During the same time span, clothing costs increased 66%; transportation, 112%; housing, 127%; food, 128%; and medical, 140%. The cost of informational products in the form of books and journals is rising nearly as much as the cost of energy. We have recognized the importance of energy and the grim reality of its rising cost and we are coming to terms with it. Similarly, we must recognize the value of information, especially that which is used to facilitate the provision of health care, and come to terms with its rising cost.

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Because of the need for up-to-date information by health personnel, two-thirds of the typical medical library collection consists of serials, including some foreign journals. It is impossible to meet the increasing costs required by merely maintaining current serial subscriptions, and new and important journals become available each year. Medical librarians are finding themselves devoting more attention to cancellation of subscriptions due to a lack of funds than to the selection of library materials for acquisition. The MLAA in its 17-year history has been restricted by a consistently low funding level. A cursory review of funding for the MLAA over the past few years reveals fairly steady annual appropriations of approximately $10 million. Funding for FY 1982 has adversely affected the MLAA program. Before FY 1982, the appropriations appear to represent consistent funding for these programs, but consideration of this funding level in terms of constant dollars (based on biomedical R&D price index) represents a decline in support of 50% from 1969 to 1979. Therefore, establishing a funding ceiling for the MLAA at $10 to $12 million for the next three fiscal years is not excessive; it is minimal.

IMPACT OF THE MLAA ON THE NATION'S HEALTH CARE EFFORTS

Renewal of the MLAA is essential to the nation's health practitioners, researchers, and educators. We have become an information-based society, and no where is the need for timely delivery of information more important than in the health care field. Practicing clinicians are dependent on the rapid transfer of information concerning new treatment regimens and discoveries in research which can benefit their patients. This information should be readily available to health professionals even if they are geographically distant from modern library facilities.

Few in this nation question the value of biomedical research to citizens, but the importance of disseminating this information is not always recognized. Research results must be distributed to benefit society and, indeed, research is incomplete until it has been documented and published. The research scientist's use of library resources to find scientific and technical information streamlining research methodologies by excluding techniques previously proven ineffective. It is common knowledge that the inventions of the jet airplane and the communications satellite have turned the world into a "global village" with the capability of instantly-shared communication now a reality; the same is true for the biomedical research system, which is now, more than ever, international in scope. Last year, Dr. Donald Frederickson pointed out that the National Library of Medicine is the world's principal curator for biomedical-research information, and nearly every country uses and contributes to its programs for data collection and retrieval. As he noted, demands for data management are rising rapidly, with new technical achievements in research creating marked increases in the need for information handling systems.[1]

Health educators are also dependent upon information services. Medical libraries not only provide instructional materials for students, but also materials for the continuing education of health practitioners, information resources for academic training programs geographically separated from health schools, and audiovisuals to teach laboratory and treatment techniques to dental, medical, and nursing students.

The MLAA's programs have significantly contributed to improving biomedical

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information services for patient care and research. Resource grants have provided invaluable "seed monies" to establish consortia in rural areas to provide information services for health practitioners through the combined efforts of local libraries. Resource grants have also encouraged the development of new services such as the "circuit" librarian, who provides information services for several small, rural hospitals, and the clinical medical librarian, who attends rounds and serves as the information resource for a health care team. The value of this latter service is evidenced by an article in the Journal of the American Medical Association, which reported that the information supplied by the clinical librarian in one hospital over a five-month period affected patient management in 20% of the cases.[2] Current MLAA research and training grants are supporting projects to study clinical decision making, to develop individualized library services for medical office practice, and to support training for researchers in biomedical communications to bridge the gap between modern computer technology and the information needs of the clinician. MLAA's Regional Medical Library Program supports health information services in rural areas by outreach programs to train local library personnel, to provide back-up reference services and to supply, through interlibrary loan, materials which are unavailable locally. The development of the Regional Medical Library Network has also resulted in more efficient delivery of biomedical research information to the scientist and stimulated the growth of more sophisticated research reference services to provide information for research inquiries.

THE NEED FOR FEDERAL SUPPORT

Federal support through the Medical Library Assistance Act is essential for continued progress of the nation's medical libraries in meeting the information needs of the health care community. Many of the activities supported by MLAA programs could not be undertaken without the assistance provided. Federal support through the Resource Improvement Grants Program provides short-term, non-renewable grants, with matching funds provided by the institutions, to establish new information services. These demonstrations are later continued through local funding. Resource Project Grants support the initiation or development of new services, such as the clinical medical librarian services described earlier, which are then implemented in other medical libraries throughout the nation without federal support. And, as Dr. Frederickson pointed out in his article on biomedical research in the 1980's, history has already proven that private sources cannot be relied upon to support research if federal support is withdrawn. Research and training programs which explore the role of developing computer technology in organizing and delivering biomedical information are necessary if medical libraries are to take advantage of new methods of information handling in providing effective information services.

Federal support for the Regional Medical Library (RML) Program is especially essential. This national network of eleven Regional Medical Libraries, 103 Resource Libraries, and more than 3,000 local health sciences libraries provides a coordinated, decentralized program for delivering biomedical information services.

The Board of Regents of the National Library of Medicine approved a proposed reconfiguration of the Regional Medical Library Program. Beginning in November 1982, the present 11 regions will be reduced to 7. This is the first major change in the network geographic boundaries in the program's 14-year history. Over the past 5 - 6 years the available funds through the Medical Library Assistance Act have been relatively constant at around $3 million a year. The reconfiguration

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came about, in part, as a result of the rise of administrative and indirect costs which reduced the amount of money available for direct RML services and programs. The reconfiguration was also necessitated by reduced funding in FY 1982 for the HLAA.

The original legislation for the HLAA provided for the establishment of Regional Branches of the National Library of Medicine; however, the National Library of Medicine felt it was more cost effective to provide regional services through contract support to existing libraries, building on existing resources by encouraging them to serve as "Regional Medical Libraries." Most Regional Medical Libraries are university-based institutions which have been selected competitively from libraries with well-trained personnel, strong collections, and good service records. The RMLs serve as a major regional link in this country's Biomedical Communications Network in communicating between national and local institutional levels.

Development of the Regional Medical Library Network has had profound effects on the National Library of Medicine, which now serves as part of this national medical library network. Its role has evolved from being the library to which every institution turned, as it was in the years before the HLAA, into its current role of leadership in the Biomedical Communications Network. It is the comprehensive national resource, providing materials not available in regional or local collections, and, as the national medical indexing and cataloging center, saving the nation millions of dollars annually by sharing the products of its labor-intensive cataloging efforts with libraries throughout the network. Two essential information service functions of the National Library of Medicine (interlibrary loan and online searching services, such as MEDLINE) have been decentralized as the RML network developed, thus allowing the National Library of Medicine to devote more of its efforts to national information services concerns and to the improvement of local self sufficiency: in FY 1981, for example, libraries participating in the RML network provided nearly two million interlibrary loans to each other; the National Library of Medicine filled approximately 190,000 of these requests, or slightly less than 10% of the total.

PROGRAM RECOMMENDATIONS

As stated earlier, the Medical Library Association strongly supports renewal of all HLAA programs. Of particular interest are four programs which most directly affect medical librarianship: the Regional Medical Library Program, and the Resource, Training, and Research grant programs. An outline of recommendations for all programs follows:

The Regional Medical Library Program. This is the most significant of the HLAA programs in terms of its impact on the national coordination of medical library services. The HLAA provides contract support for the Regional Medical Libraries. These libraries coordinate regional health information services and are an important part of a hierarchical national network of libraries which share their resources through interlibrary loans, union lists of journal holdings, and shared cataloging and acquisitions programs. They also share human resources through consultation. training, and continuing education programs.

The RML Program has had a substantial positive impact in improving medical library services. Significant evolution of the program has occurred in response to changing conditions and demands, and this process will continue as the program responds to the needs of the health sciences community.

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If the goal of rapid delivery of biomedical information is to be fully realized, however, the network established by the Regional Medical Library Program must be refined and expanded. Only half of the nation's health institutions participate in this network. There are a significant number of health care institutions without information resources and personnel. These must be reached through the RML Program's outreach services. No citizen's well-being should suffer due to the lack of access to known medical knowledge. Additional funds are needed for an increase in reference services, for emphasis on consultation and educational programs, to support work on the establishment of library standards and more extensive lists of serial holdings, and to broaden participation in shared cataloging projects. The cooperative efforts of the nation's medical libraries through participation in the RML program have been outstanding, and significant savings to the nation's health care system have resulted from RML resource-sharing programs. Federal funding is more than matched by the donation of thousands of manhours in staff time by participating libraries to further RML Program objectives. Reduced funding for the Regional Medical Library Program could have a profound negative affect on the nation's medical libraries' ability to continue to participate at the present level in the sharing of health information.

Present funding for the Regional Medical Library Program is $2.5 million. Although it is recognized that increased support for the Regional Medical Library Program must be provided if the program is to move ahead, the recommended authorization level of $10 million beginning in FY 1983 would allow no increases over the FY 1981 annual expenditures of $3 million for this program.

Resource Project and Improvement Grants. The Resource Grant Program provides seed monies for expanding and improving basic medical library services. This program has encouraged consortia of local libraries to provide medical information services, to share resources and to save costs. The resource grant provides initial incentive to establish an information service and cooperation; it is continued with local support.

Libraries are labor-intensive institutions. Resource grants have also been used to support and to adapt advances in computer technology to library operations. Far too many medical libraries still lack access to computerized cataloging systems or machine readable serials records. These systems, as well as online catalogs, are technically feasible, but they are still far from reality because of inadequate support.

With less than two million dollars spent annually on all resource grants, it is understandable that progress in all these areas has not been as rapid as might be desirable. Increased funding is badly needed for this program. The Association, recognizing the need to control inflation, is recommending a minimum $1.6 million for FY 1983.

Research Grants. These grants support projects investigating basic issues in biomedical communication and health sciences information. Areas for research and development include librarianship, information science, computer science, and other disciplines dealing with information management in health settings. Since FY 1979 the National Library of Medicine has stimulated through its Computers-in-Medicine Program a greater research effort into the relationship of information needs of health personnel to information delivery systems. Additional research support is needed to translate these research findings into innovative library information services.

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Improved research funding for medical libraries could provide for the development of new and improved communications systems and more thorough evaluations of the effectiveness of information services. With computer terminals readily available in many medical libraries for use in online searching services, the feasibility of using "electronic mail" systems to link medical libraries should be explored.

Medical librarians should also join with health educators to investigate more thoroughly such topics as the relation of library user instruction to student performance and innovative means of disseminating information for the continuing education of health professionals. A stronger research program would greatly benefit medical libraries and the study of biomedical information collection, organization and dissemination. MLA would prefer to recommend considerably increased funding for the research program to advance library operations and services. The actual recommended funding level of $10 million for FY 1983 will only permit the same expenditure for research as FY 1981--$2.7 million.

Training Grants. Continuation of this program authority is essential. The tremendous volume and complexity of health information, coupled with new developments in computer and communication technology, require new systems and techniques for the organization, interpretation, and dissemination of information to all health professionals. The training grant program currently supports training for health professionals and computer specialists in the application of computer technology to health science problems. Advances in computer technology are making a tremendous impact on the health sciences and health sciences librarianship. The training of librarians as well as scientists in this area is vital if we are to work together on these information systems in the future.

The Medical Library Association recommends that $1.6 million be expended for training in FY 1983. These funds, though minimal, present training programs in computer technology and to initiate training for medical librarians to enable them to effectively integrate technological advancements with the delivery of information services.

Publication and Special Scientific Projects. Continuation of these two program authorities is also important. These programs provide short-term support for nonprofit publications and scholarly works of importance to the national health effort. These works are important contributions to medical knowledge but, because of their narrow subject scope (and, subsequently, relatively small market), they are not profitable for commercial publishers. In fact, their prospects for profitable publication commercially are considered before grant support is given. Provision for making such works available to the health field should continue by renewal of these program authorities. Once again, the Association's recommended reauthorization level would allow only for support for these two programs at the FY 1981 expenditure levels.

THE COST RECOVERY ISSUE AND THE GOVERNMENT'S ROLE IN THE PROVISION OF INFORMATION SERVICES.

Considering the debate over the appropriate roles in the government (public sector) and the private sector vis-a-vis provision of information services, the Medical Library Association is heartened that no language relating to full cost recovery

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for the National Library of Medicine's information products and services is included in this legislation. The National Library of Medicine Act of 1956 directs the library to acquire books, periodicals and other materials; to organize them by appropriate cataloging and indexing; and to publish and make available the information contained in these materials.

The fundamental rationale for the NLM's legislative missive recognizes that: (1) health is a national priority; (2) health research is a major national investment; (3) dissemination of information derived from health research is essential to realize the full benefit from the investment in research; and (4) every possible means should be taken to stimulate the effective dissemination of that information. In that context, the legislatively mandated responsibility of the NLM is to provide the means for assuring ready dissemination of research results. The costs of doing so are a national investment as important as the overwhelmingly greater investment in the research. Surely the costs associated with acquiring, indexing, and processing health information by the NLM in fulfillment of its mission should not be recovered in service fees charged to users, whether from the private or public sector. Data base creation costs should continue to be viewed as a national capital investment for the public good, supported indirectly by tax dollars from both the private and public sectors. Access and reproduction costs, however, should be borne by direct users of NLM's data bases. In this way, equal access to information collected, compiled, organized, and disseminated by the government will be assured.

SUMMARY

The American people are spending billions of dollars on medical research; it must be realized that the effectiveness of these research efforts will continue to be severely compromised unless better support is given to medical libraries to organize and disseminate the information generated by this research to improve health care delivery. S.2311 clearly does not provide adequate support for the programs of the Medical Library Assistance Act. The Medical Library Association recommends a three-year renewal of all six programs at funding levels of $10, 11 and 12 million for FY 1983, 1984, and 1985, respectively.

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TESTIMONY FOR THE RECORD

OF

ERNST R. JAFFÉ, M.D.

CHAIRMAN, PUBLIC EDUCATION COMMITTEE

AMERICAN SOCIETY OF HEMATOLOGY

AND

PROFESSOR OF MEDICINE, ALBERT EINSTEIN COLLEGE OF MEDICINE

AND

HEAD, DIVISION OF HEMATOLOGY

BRONX, NEW YORK

MARCH 31, 1982

BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES

UNITED STATES SENATE

WASHINGTON, D.C.

Chairman Hatch, and Honorable Members of the Committee:

On behalf of the American Society of Hematology and its 3,000 members, I extend to you our sincere thanks for granting me the privilege of presenting testimony before this Committee in connection with the legislation for the reauthorization of the National Heart, Lung, and Blood Institute and biomedical research.

I am Dr. Ernst R. Jaffé. I am the Head of the Division of Hematology in the Department of Medicine, as well as Professor of Medicine, at the Albert Einstein College of Medicine, Bronx, New York. I am also the Chairman of the Public Education Committee of the American Society of Hematology. This Society, the only national organization of hematologists, is comprised of physicians and biomedical scientists who are concerned with research, patient care, and teaching activities as they relate to blood.

Before discussing our views about this legislation, I would like to take this opportunity to express our thanks to you, Mr. Hatch, and your associates for your staunch support and efforts on behalf of biomedical research and hematology. We greatly appreciate your long-standing commitment to the programs of the National Institutes of Health. You have consistently demonstrated your concern about the health of the American people with your understanding and appreciation of the vitally important role that basic and clinical research play in achieving improvements in our well being.

We have had an opportunity to review the provisions of the bill that has been introduced as they relate to the NHLBI.

We note with pleasure that the provision of Section 419B (287i) has been maintained so that "not less than 15% of such sums shall be preserved for programs under this part for programs respecting blood diseases and blood resources." We trust that this 15% authorization will be looked upon as a floor or minimum, and not a ceiling or maximum.

I would now like to spend just a few minutes to summarize briefly a small fraction of the recent exciting and important advances that have been made in the research programs supported by the NHLBI and that relate to hematology, blood diseases, and blood resources.

1. A major clinical trial has demonstrated that a vaccine against hepatitis B virus provides nearly complete protection against this debilitating and sometimes fatal disease. Mass immunization may ultimately reduce the incidence of acute hepatitis B and its chronic carrier state, as well as the mortality from chronic active hepatitis, cirrhosis, and liver cancer.

2. An exciting and very promising new technology has been advised that should provide important detailed information about the life-threatening iron overload that develops in patients with Cooley's anemia and other anemias requiring repeated blood transfusions. This non-invasive method, obviating the need to obtain tissue biopsies or even blood samples, will accurately measure the amount of iron in the liver and, perhaps, the heart, and will permit the evaluation of present and newly developing treatments designed to remove the excess iron. The technique, however, requires further study to establish clearly its validity and reliability.

3. The ability to determine the degree to which simple sugar is bound to hemoglobin, the oxygen-carrying pigment of red blood cells, has provided a new means by which to follow the control achieved in patients with diabetes. A recent improvement in methodology now permits the use of this change in subjects with abnormal hemoglobins, such as sickle cell hemoglobin, as well as in those with normal hemoglobin. These results demonstrate the important interrelationship between research on blood and its components and other human disease processes.

4. Studies of a blood-clotting factor from pig blood have shown that it (Factor VIII) can be freed rather easily of undesirable properties so that a pure and less expensive material can be obtained to treat certain patients with hemophilia and other related bleeding disorders. Clinical trials, however, are urgently needed to validate the initial findings.

5. A new enzyme, hementin, has been isolated from the salivary gland of a leech, and gives promise of providing a different and, perhaps, better means by which to dissolve blood clots even after they have formed or become lodged in the heart, lung, or brain.

6. Important new information has been obtained about how human hemoglobin is changed from the fetal form in the red blood cells of the unborn child to that of the adult. These findings may make it possible to develop a rational and safe means by which to treat patients with inherited defects in the manufacture of adult hemoglobin so that they will make more of the fetal oxygen-carrying pigment that will permit more normal lives for those with Cooley's anemia and similar disorders.

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7. Patients who receive kidney, bone marrow, or heart transplants frequently develop severe and even fatal infections with a certain virus, cytomegalovirus. It has been shown that antibodies against this virus can be prepared as immune globulin from selected portions of normal human plasma in sufficient amounts to permit clinical trials of its efficacy in preventing or modifying this infection.

8. Progress has been made in developing an indirect method for screening blood donors for the presence of non-A, non-B hepatitis virus, now the major cause of this serious disease that can follow on blood transfusions. Elimination of such carriers would further enhance the safety of blood transfusions.

9. Studies on how platelets, the tiny pieces of cells in the blood that are intimately involved in blood clotting, make and release a fatty acid, arachidonate, herald the possibility of altering this metabolic process in order to decrease or prevent undesired blood clots that lead to strokes and heart attacks.

These nine examples cover a broad spectrum of advances. Note that some are essentially completed, while others are still in early exploratory stages. The former need to be finished and provided, where appropriate, on a broad scale. The latter must be continued to make sure that the initial successes can be confirmed and repeated by others and can be made practical for the appropriate groups of American citizens. Funds authorized and ultimately appropriated for these purposes will surely not be wasted.

Although the NHLBI provides the largest share of funds for blood research, I must make note that the National Institute of Arthritis, Diabetes, Digestive and Kidney Diseases (NIADDKD) and the National Cancer Institute (NCI) also have major commitments to the advancement of biomedical science in this area.

Eighty percent of all blood-related research has been supported by these three Institutes, but 20% has derived its resources from the other eight Institutes. We would, therefore, very much like to see this multiplicity of support mechanisms for blood research continued. This concept has been clearly recognized by Congress recently. For example, in the bill report language that accompanied the Senate's Committee on Appropriations measure on the Labor/DHHS/Education Departments' appropriations, H.R. 4560, last year, the following statements appeared. "The Committee has learned of the excellent progress being made in hematologic research in both the Heart and Arthritis Institutes. It understands that the Division of Blood Diseases and Resources of the Heart Institute is most concerned with fundamental hematologic research and its clinical applications, while the latter Institute's blood program emphasizes the mechanisms of normal blood cell functions and their alterations in disease process. The hematology program activities in these institutes are closely coordinated and complementary to each other. Thus, the Committee expects that hematologic research will continue to be supported by both Institutes." We sincerely hope that this type of language can be included in the report about the legislation now under consideration in order to make it clear that blood, which is all pervasive in both the body and the NIH, merits support wherever its disorders may become manifest.

Finally, I would like to read into the record a resolution that was passed unanimously at the annual meeting of the full membership of the American Society of Hematology last December 8th. "The Society expresses its concerns regarding the current government funding recommendations and practices for supporting

biomedical research and training, and emphasizes their disastrous short-term and long-term implications for intellectual and scientific progress, for the health of American science and education, and for the health of the country." This Committee, and other members of Congress have, most fortunately, recognized these hazards and taken corrective action.

My colleagues and I in the biomedical community thank you, Mr. Chairman, and the members of your Committee for your kind attention to our presentation. We can assure you that the blood research work proposed for the near and distant future will be done by those who have been, and will be, trained to do it. We thank you again for recognizing the past accomplishments and for providing us with the means necessary to go forward.

RE-AUTHORIZATION OF THE NATIONAL HEART, LUNG AND BLOOD INSTITUTE

Testimony Presented By:

Alfred Munzer, M.D.
Member of the Board of Directors of the American Lung Association and the American Thoracic Society

On behalf of

American Lung Association/American Thoracic Society

House Committee on Energy and Commerce
Subcommittee on Health and the Environment

Washington, D.C.
March 29, 1982

Mr. Chairman, Members of the Subcommittee:

My name is Alfred Munzer and I am a physician specializing in diseases of the lung and a member of the Board of Directors of the American Lung Association of its Medical section, the American Thoracic Society and I speak for both today.

The American Thoracic Society is an 8,500 member scientific organization dedicated to the acquisition and dissemination of knowledge about the lung. The American Lung Association is the nation's oldest voluntary health agency and is committed to the prevention and control of lung disease.

We have joined with other major health organizations in supporting the broad principles of re-authorization of the National Heart, Lung and Blood Institute, and a jointly endorsed letter was sent to the Chairman and members of the Subcommittee.

Today I will confine my remarks to those aspects of the Health Research Act of 1982 that specifically deal with lung disease. The leaders of the organizations I represent have not yet had the opportunity to carefully assess all aspects of H.R. 5919 and we may wish to submit a supplementary statement before the record of this hearing is closed.

We have anticipated NHLBI re-authorization and for the past six months a distinguished ALA/ATS Task Force on Federal Lung Research has been at work to develop our positions. The Task Force's report is a comprehensive review of the magnitude of the lung disease problem, the scope of the federal lung research commitment, the accomplishments of the past decade and the opportunities for important new research accomplishments. It is submitted for the record.

I speak here, Mr. Chairman, with the bias of a practicing physician who day-after-day faces the anguish of patients who because of lung disease cannot breathe. Lung diseases are a devastating health problem in the United States. They rank third among the leading causes of death and sixth among the conditions responsible for early retirement because of disability. Worse, while there has been a decline in the mortality from all causes of death, the mortality from lung disease has continued to rise. The annual cost of lung disease has been estimated at $45 billion dollars.

But grim as the picture may be, it is not hopeless. Basic and applied lung research, supported predominantly by the Federal Government, has already greatly improved detection and treatment of many diseases. Furthermore, there are many exciting advances in our understanding of lung function that are at the threshold of being translated into new forms of treatment for patients with lung disease.

The lung research program within the National Heart, Lung and Blood Institute has proven to be a scientifically advanced and fiscally sound program that has led to a new understanding of such diseases as: chronic bronchitis, asthma, emphysema, and pulmonary fibrosis. The American Thoracic Society and the American Lung Association therefore support re-authorization of the NHLBI. We also support retention of the provision that <u>at least</u> 15% of funds expended for extramural programs must be for lung programs. It is essential this 15% be a floor and not a ceiling on lung research.

Where we particularly feel improvement can be made at this time in federal lung disease research is by focusing on a better interagency coordination and communication. H.R. 5919 addresses this issue with respect to other diseases and we ask that the same principle be applied to lung problems. Approximately half of the lung research expenditures in 1979 were in federal agencies other than NHLBI. It is critical that the Government assure itself that limited resources available are applied to true priorities and with greatest efficiency.

It is our recommendation that strong interagency overview of all federal programs that have components dealing with lung disease be established under the Director of the Division of Lung Diseases. This Interagency Committee on Lung Diseases would report annually to the HHS Secretary, the NIH Director and NHLBI Advisory Council. Furthermore, to insure strong scientific guidance, the Pulmonary Disease Advisory Committee of the Division of Lung Disease should also relate to this Interagency Committee on Lung Diseases. There should also be established within the NHLBI Advisory Council a subcommittee on lung diseases to recommend to the Council such changes in the administration of the Lung Program as may be deemed necessary.

The present unstructured approach to investigation and investigational training for lung diseases allows for duplication of efforts on the one hand, and missed opportunities for fruitful investigation on the other. The proposed organization would provide for developing a coordinated plan in research and training in lung diseases including:

(a) recommendations for expenditures for each of the National Research Institutes within the NIH;

(b) assessing the adequacy of management practices within those institutes and developing improved approaches where needed;

(c) monitoring and reviewing lung expenditures by such institutes, and;

(d) identifying research opportunities and recommending ways for their implementation.

Ultimately, we feel the best way to ensure adequate funding and coordination of lung research would be the establishment of a separate lung institute. For now, however, we feel the changes I have outlined would be the logical next step.

There is one additional proposal, that in the opinion of the Task Force will make a substantial difference in lung disease. The knowledge is at hand to mount a sorely needed attack on chronic obstructive pulmonary disease (COPD), the most rapidly rising cause of death in the United States. Similar strategies can be applied to cystic fibrosis, the most common chronic fatal respiratory disease of children. Because the regular NHLBI budget cannot be stretched to cover the major new initiatives that are needed against COPD and cystic fibrosis, we recommend that an additional $15 million dollars above the regular NHLBI authorization be set aside for that purpose. Such an offensive would make it possible to reverse the COPD trends by 1990.

The American Thoracic Society and the American Lung Association are well aware that a supply of investigators with a medical degree

is essential to basic and clinical investigation. There is, however, a nationwide decrease of such investigators that will impede basic investigation and the translation of that investigation into patient care. We urge Congress and the Administration to support continued development of manpower to carry out basic and applied research.

Our final recommendation is that research in occupational lung diseases and the effects of environmental factors on the lung be expanded in all Institutes presently responsible for these investigations. The 1980's have been called the decade of environmental and occupational concern and commitment. The lung is the target for most occupational and environmental exposures. Funding for research is clearly inadequate to provide the answers to a host of preventable lung diseases.

Mr. Chairman, in the past decade there have been important clinical advances as a result of the application of knowledge gained from basic research. Neonatal Respiratory Distress Syndrome is just one exciting example. There are other diseases in which important clinical advances could be made, by taking advantage of knowledge gained from recent basic research. Some examples are: pulmonary emphysema, cystic fibrosis, interstitial pulmonary fibrosis and circulatory disorders. The list of diseases in which more basic research is necessary before important clinical advances can be made include some of the most critical respiratory conditions: cancer of the lungs, occupational lung diseases, and environmental lung diseases.

The question comes down to whether we are willing to make the necessary structural changes in the federal biomedical research program to assure optimum use of the severely limited resources for lung research. The opportunities are real and practical.

Thank you.

STATEMENT

by

DONALD C. HARRISON, M.D.
PRESIDENT
AMERICAN HEART ASSOCIATION

to the

UNITED STATES SENATE

Committee on Labor and Human Resources

on

S. 2311, Biomedical Research, Training and Medical Library Assistance Amendments of 1982

March 31, 1982

AMERICAN HEART ASSOCIATION
SUMMARY OF STATEMENT ON S. 2311

Biomedical Research, Training and Medicine
Library Assistance Amendment of 1982

1. The American Heart Association strongly recommends:

   - that the unique isolation of Prevention, Education and Control Programs from other NHLBI programs be resolved by deleting the separate authorization in Section 414 (b) of S. 2311.

   - and, therefore, that there be authorized to be appropriated for NHLBI, $750,000,000 for FY 83, $838,000,000 for FY 84 and $947,000,000 for FY 85. (These amounts to combine the separate authorizations for NHLBI and for Prevention, Education and Control Programs.)

2. The American Heart Association strongly supports the provision in Section 201 of S.2311:

   - that repeals the NRSA recipient "payback requirements" in Section 472 (c) of the current act.

3. The American Heart Association recommends:

   - that clarifying language be added to the current act to ensure that National Research Service Awards be treated as fellowships, rather than income.

   - that NRSA budget authority be extended for a period of three years.

   - that there be authorized to be appropriated for National Research Service Awards $205,000,000 for FY 83, $232,000,000 for FY 84 and $263,000,000 for FY 85.

4. The American Heart Association strongly recommends:

   - that there be authorized to be appropriated for support of the National Library of Medicine $8,500,000 for FY 83, $9,000,000 for FY 84 and $10,000,000 for FY 85.

5. The American Heart Association endorses the provision in Section 203 (c) (10) of S. 2311:

   - to establish within the Office of the Assistant Secretary for Health an Office of Disease Prevention and Health Promotion.

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6. The American Heart Association recommends:

   - that there be authorized to be appropriated for payments of grants and contracts under Section 1701 (b), $3,500,000 for FY 83, $4,000,000 for FY 84 and $4,500,000 for FY 85.

7. The American Heart Association endorses the provisions in Section 204 (a) of S. 2311:

   - to extend the authority of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research through December 31, 1983.

8. The American Heart Association recommends:

   - that there be authorized to be appropriated for the commission, $5,000,000 for FY 83.

Donald C. Harrison, M.D. -- American Heart Association 3/31/82

The American Heart Association, a national voluntary health organization that represents more than 119,000 voluntary leaders of 55 affiliated components, more than 40,000 scientific members and more than 2 million program and fund raising volunteers, is please to have this opportunity to provide the following comments on S. 2311, the "Biomedical Research, Training and Medical Library Amendments of 1982."

We have reviewed the authorizing legislation in the context of what we believe to be the Committee's rationale for strong support of biomedical research and the alignment of programs within the Office of the Assistant Secretary for Health.

We are pleased to note that S. 2311 proposes reauthorization of NHLBI for a period of three years. We believe the energies and expense required for annual reauthorization can better be applied to carrying out the mission for which NHLBI was established.

The American Heart Association is deeply grateful to the members of the Senate Committee on Labor and Human Resources and to the other health leaders in Congress for the consistent and steadfast support of federal programs in biomedical research and prevention.

As Secretary Schweiker has stated, the National Institutes of Health are a "unique national resource" and must be preserved as such. The American Heart Association agrees; we believe that our nation is endowed with a wealth of scientific and technological capability which since mid-century has brought us to a position of scientific leadership second to none in the world.

The American Heart Association has been privileged to play an active part in this movement, in part through of our own programs of research, education and prevention, and in part by means of our support of the NHLBI and its effective programs.

As I am certain the Committee is well aware, the evidence of this accomplishment is clear. I refer to the recent declines in death rates from cardiovascular disease and stroke.

In the years from 1968 to 1978, mortality rates from coronary heart disease in the United States decreased more than 25 percent. Mortality from stroke plummeted at the rate of five percent per year. Overall cardiovascular mortality in men aged 35 to 74 has declined by almost 30 percent.

In 1969 the United States had the highest death rate from coronary heart disease among 27 industrialized nations of the world with 865 deaths per 100,000. Thanks to the rapid developments in scientific knowledge which took place in earlier decades, our nation dropped in 1977 to seventh place, with a death rate of 670 per 100,000.

As Dr. Robert Levy, then Director of NHLBI, said in September, 1981, "If these death rates had not changed, a million more Americans would have died in the 1970's, but instead a million lives were saved."

I hasten to point out that the battle is far from won. Cardiovascular diseases still account for almost a million American deaths per year -- more than all from

other causes combined. Science still does not know the causes of cardiovascular diseases, nor can we absolutely cure or prevent them as yet.

The American Heart Association wishes to make it clear that in our judgement, the recent decline in the rate of death from heart diseases and stroke is due directly to the scientific advances which took place in the preceding decades -- the 1950's and 1960's.

As the NHLBI Advisory Council was told by Acting Director Dr. Peter Frommer in February, 1982, "We are harvesting seeds we have sown, but we are not planting a new crop."

We agree and note with alarm the failure of federal funding to keep abreast of inflation in recent years. This has resulted in a shortfall in the continuing development of basic scientific understanding of the processes which produce heart attack, hypertension, sudden cardiac death and stroke.

We believe that to continue to encourage the decline in mortality it is necessary to continue the application of research knowledge; however, in order to produce the scientific progress in years ahead we cannot slack in our efforts to seek the answers to basic scientific questions.

This need to continue both of these important approaches was aptly stated by Dr. Richard Remington, Dean of the University of Michigan School of Public Health in November, 1981.

Dr. Remington entitled his lecture, "Choices that Must Not Be Made." He emphasized that we must continue both basic and applied research "directed toward better understanding and control of disease of the heart and blood vessels leading to reduction of premature death and illness."

Therefore, we urge that an increased national investment be made in research in order that our future generations are assured maximum benefits in health and life enrichment. In the field of cardiovascular diseases we have reached a state of readiness to approach much more specific ends in disease prevention than general advice about diet, exercise, smoking, etc. -- important as this advice is.

Based on specific major scientific and technological advances made in the past five years we believe we can -- if we choose to do so now -- enter a new era of investigation in the prevention of premature death from cardiovascular diseases and stroke.

This is the basis for proposing at least seven new initiatives outlined below -- four of which clearly represent new approaches to the scientific knowledge which is essential to prevention.

In past prevention studies the end points of such evaluation were death, heart attacks and stroke. Such studies required large numbers of subjects, were of long duration and were very costly. They did not examine the basic process of atherosclerosis (the obstructions developing in blood vessels supplying the heart and brain) because it was not possible to do so without considerable danger to patients in performing such studies.

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Within the past five years new methods -- such as imaging blood vessels directly and noninvasive computer techniques -- have been under development. Their application in studies which can directly alter the disease of atherosclerosis is about ready for initiation. Used together with some of the new knowledge about factors causing progression and regression of atherosclerosis, we can now institute new prevention studies in smaller patient groups and be looking at the disease process itself.

Such studies should provide answers far more quickly and more directly, and at much lower costs. This is only one example of putting our newly emerging technology and new biologic concepts to work in carrying out major new research in disease prevention.

Promising new progress is also being made in the area of hypertension, a silent killer which affects 53 million Americans. Hypertension (high blood pressure) is the most important risk factor for stroke and atherosclerosis. In its early stages it has no symptoms. If untreated it can result in serious disease complications and death.

In no other instance has basic scientific understanding and the clinical application of that knowledge been more successful in reducing death from cardiovascular disease and stroke than in the treatment of hypertension by pharmacological and other means.

However, important new knowledge is now emerging about a precursor phase of hypertension, in which basic disease mechanisms involve the central and peripheral nervous systems in the causation of essential hypertension.

It is essential that these new observations be utilized in the design of new techniques for the effective treatment of early hypertension, for the reduction of the high risk which it produces and ultimately for preventing the onset of this disease.

A third initiative in the area of prevention is a concentrated attention to studies relating to a stratification of patients experiencing myocardial infarction (heart attack). The recently concluded -- and stunningly successful -- NHLBI study which demonstrated the benefit of beta-andrenergic blockade in those patients who had no contraindication for this drug still leaves more than 50 percent of these patients for whom we have no recognized plan at this time. Considerable effort should be devoted to trying to stratify these patients. We need a major program by which we can treat those in this group who are at a high risk of sudden death. This will require a cooperative study among a number of centers.

A fourth area of prevention is the evaluation of effective techniques for smoking abatement. Some 54 million Americans still smoke cigarettes, although studies have shown that a majority would like to stop smoking. Physicians are frustrated in assisting their patients who ask for help to reduce this high risk of cardiovascular disease -- they simply do not have effective means available to do so. As Surgeon General Koop said last month in introducing his report on the Health Consequences of Smoking, "Smoking cigarettes is the most avoidable cause of death in the United States."

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A fifth area is the need to re-examine the treatment of early myocardial infarction, particularly stressing a study of streptokinase. This should be given a high priority.

A sixth area of importance is the need for basic and clinical studies to determine the etiology (the causative factors) and severity of cardiomyopathy. We are seeing increased incidence of this disease of the heart muscle and very little emphasis has been given to this syndrome.

Finally, we should step up research aimed at determining the causes and rational treatment of arrhythmias (irregular heart rhythm). Support in this area of research should range from the basic to the clinical in a variety of fields.

As I have tried to indicate in these comments, we cannot over-emphasize the need for -- and the timeliness of -- entry now into a new era of cardiovascular disease research. As I noted earlier, the decline in death rates and the millions of lives saved thereby establishes beyond question the cost-effectiveness of federal dollars which have been invested in past decades. But, only if we continue to "sow new seeds" can we expect to reap a future harvest.

The American Heart Association is well aware of the state of the economy today, and we are aware that our national resources are seriously strained. Difficult choices must be made in making and carrying out public policies. But, as Dr. Remington put it, there are some choices that must not be made.

One such choice is whether or not to invest additional federal dollars in such new prevention initiatives as I have outlined above. The American Heart Association believes that this nation cannot afford not to make such an investment.

The cost of health care in the United States continues to rise at alarming rates. Our costs for direct health care, Medicare and Medicaid and in lost wages and productivity contribute increasingly to the serious economic situation we face.

We believe that we have no other option than to do everything possible to foster the prevention of premature death and disease in our nation. The alternative is the very real possibility that the cost of treating disease in its acute and chronic aspects will in the next few decades threaten to bankrupt our nation and its citizens.

In 1948, when the National Heart Institute was initially established, the cardiovascular community had high hopes that it would address the critical need to understand the causes and to reduce premature death and disability from heart attack, stroke and other diseases of the heart and circulation. After more than four decades of splendid accomplishment the result in lives and dollars saved has more than justified that early aspiration and the federal dollars invested.

Yet, despite impressive gains in the reduction of cardiovascular mortality, support for the cardiovascular mission of the NHLBI has proportionately diminished. Since its establishment, the original National Heart Institute has been expanded to include the important additional areas of pulmonary and blood diseases. Unfortunately, there has not been a corresponding expansion in funding levels over the years.

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During the period 1972 to 1981, the DHVD extramural program (excluding clinical trials) grew at the rate of only 11 percent, in constant dollars. This is the very period in which we have seen the very positive movement in mortality trends. Our concern is that a failure in support now will reflect itself in years to come, and in terms of results that will be irrevocably lost to us.

As to how NHLBI funding has fared in recent years in relation to the other institutes, the picture is not much brighter. In the years from 1977 to 1983 the rate of increase in the NHLBI budget placed it 9th among the 11 institutes in funding growth.

During the five year period from 1978 to 1982 the NHLBI budget (in constant dollars) actually decreased at the rate of 8.8 percent. It would appear that this rate of decrease is growing; the decrease from 1981 to 1982 alone was 3.4 percent.

As a result, the award rate for approved grants-in-aid by NHLBI has dropped from 41 to 25 percent in two years, and the priority for new investigator initiated awards has fallen from 250 to 190.

We urge this Committee in the strongest terms to act now to reverse this decline in funding by providing new and higher authorization levels for NHLBI -- levels which are sufficiently high to meet the challenges and opportunities now at hand that can move us on to accelerated progress in the prevention and treatment of cardiovascular diseases.

As I have noted, we believe that the opportunities for prevention of cardiovascular disease lie within basic, as well as within applied science. We therefore find the definitions of prevention used in the language of the authorizing legislation to be too narrow and restrictive.

We strongly support continuation of the function of Assistant Director of NHLBI for Prevention, Education and Control. However, PEC programs have consisted of prevention initiatives in applied, rather than in basic science.

We believe that to mandate a separate authority for only a portion of the total spectrum of prevention is to preserve a unique and artificial isolation for PEC programs. It also tends to discourage a balanced and flexible approach to prevention of cardiovascular diseases.

We therefore suggest that the Director of NHLBI and its Advisory Council be given the authority to set NHLBI prevention priorities that are based on the "state of the art" and to determine the appropriate allocation of funds to prevention, education and control programs, rather than to mandate these decisions in statute.

The American Heart Association strongly recommends:

- that the unique isolation of prevention, education and control programs from other NHLBI programs be resolved by deleting the separate authorization in Section 414 (b) of S. 2311.

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- and that therefore, there be authorized to be appropriated for NHLBI, $750,000,000 for FY 83, $838,000,000 for FY 84 and $947,000,000 for FY 85.

The American Heart Association is seriously concerned that the Internal Revenue Service classification of National Research Service Award grants as "taxable income" effective January 1, 1982 will discourage young physicians and scientists from entering or continuing a research career.

We are alarmed at the present inclination of bright young scientific minds to move away from a future career in biomedical research. We must protect and nuture the cadre of young career scientists who alone can resolve our scientific future in decades to come. Exempting NRSA grants from taxation seems a small price to pay for this.

The American Heart Association, therefore strongly supports Section 201 of S. 2311:

- that repeals the NRSA recipient "payback requirements" in Section 472 (c) of the current act.

The American Heart Association recommends:

- that clarifying language be added to the current act to ensure that National Research Service Awards be treated as fellowships rather than income which is subject to taxation.
- that the NRSA budget authority be extended for a period of three years.
- that there be authorized to be appropriated for National Research Service Awards, $205,000,000 for FY 83, $232,000,000 for FY 84 and $263,000,000 for FY 85.

Since its establishment within the Public Health Service in 1956, the National Library of Medicine has carried out a distinguished program of systematized medical and scientific information gathering and distribution. Scientific information is being generated today at record rates. It is critical to the advancement of science that the access to, and the utilization of these important data be at maximum levels.

The American Heart Association strongly recommends:

- that there be authorized to be appropriated for support of the National Library of Medicine $8,500,000 for FY 83, $9,000,000 for FY 84 and $10,000,000 for FY 85.

As I have noted above, we believe that the effective application of existing scientific knowledge to prevent premature illness and death is necessary if we are to continue to reduce mortality and reverse the ever-increasing costs of treating chronic diseases.

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The Office of Disease Prevention and Health Promotion (ODPHP) in the Office of the Assistant Secretary for Health has been effective in its apprcach to the gathering and dispensing of health information and the promulgation of disease prevention and health promotion through such publications as "Promoting Health/-Preventing Disease: Objectives for the Nation."

S. 2311 provides a statutory authority for ODPHP, simplifies its structure and strengthens and clarifies its functions.

The American Heart Association endorses Section 203 (c) (10) of S. 2311:

- to establish within the Office of the Assistant Secretary for Health an Office of Disease Prevention and Health Promotion.

The American Heart Association recommends:

- that there be authorized to be appropriated for payment of grants and contracts under Section 1701 (b), $3,500,000 for FY 83, $4,000,000 for FY 84 and $4,500,000 for FY 85.

The American Heart Association endorses the provisions in Section 204(a) of S. 2311:

- to extend the authority of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research through December 31, 1983.

- and recommends that there be authorized to be appropriated for the Commission, $5,000,000 for FY 83.

The American Heart Association is deeply grateful for this opportunity to offer these comments and for their consideration by the Committee on Labor and Human Resources.

Donald C. Harrison

Donald C. Harrison, M.D.
President
American Heart Association

TESTIMONY

On Behalf

of

THE AMERICAN CANCER SOCIETY

Before

The Labor and Human Resources Committee
United States Senate

ROBERT V.P. HUTTER, M.D.

President
American Cancer Society

March 31, 1982

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TESTIMONY OF ROBERT V.P. HUTTER, M.D.

Mr. Chairman, members of the Committee, as President of the American Cancer Society, I am privileged to present testimony on behalf of the organization, a voluntary health agency with over 2 million active volunteers. The Society strongly supports a single reauthorization of the National Cancer Act at a funding level that will permit the National Cancer Institute and those of us who are practicing physicians working in the cancer area an opportunity to continue and to surpass the progress made during the last decade.

I know there are many who say that progress has not been made in cancer treatment and prevention. There are those who question the national cancer program and who question the resources we, as a nation have committed to that program.

We at the American Cancer Society believe that the last decade has seen remarkable achievements in the treatment and prevention of cancer. This is especially true in childhood cancers, which while they may not be the most prevalent are certainly among the most heart rending.

In 1960 if one of your children or grandchildren had been diagnosed as having acute lymphocytic leukemia that child would have had one chance in one hundred to live for 5 years. Today, a young leukemia patient's chances for 5-year survival are 50 percent and still improving. In fact, now more than half of all children with a variety of cancers can expect to live a normal

life free of disease. Children with cancers of the bone and connective tissue, such as Ewing's sarcoma and rhabdomyosarcoma, once were cured only 10 to 20 percent of the time. Now, surgery, followed by local radiation therapy and chemotherapy to halt distant spread of cancer cells, can cure 60 to 70 percent of children. Surely, that statistic alone is worth whatever money we have spent to further research and treatment in this area.

In 1981 110,000 women were discovered to have breast cancer, (one American woman in 11 will develop breast cancer), and more than 37,000 women died of breast cancer. Today chemotherapy is used as a sequel to surgery or radiation therapy as well as in cases of recurrence or metastasis and these drugs are beginning to boost survival rates that have been unchanged for 30 years. Although trends already are apparent, the statistics that reflect increased survival are expected to become even more dramatic in the next 5 to 10 years. This new hope for survival is coupled with innovations in reconstructive surgery and more often with less radical initial surgery making the disease less feared. Women are now more encouraged to do what is necessary to ensure early detection and are availing themselves with greater frequency of such detection techniques such as the use of mammography.

Hodgkin's disease, a lymph node cancer, is now curable in the overwhelming majority of patients due to the development and skillful use of radiation therapy and drug treatment. Over 80 percent

of patients with localized disease are cured by radiotherapy while half of those with advanced disease involving the liver, bone marrow, lung, or other organs, are surviving for long periods with combinations of drugs. There are, in addition, several other cancers of the lymphatic system which are now curable with radiation therapy and combinations of drugs. Diffuse histiocytic lymphoma, one of the most serious of these cancers, now can be cured in half of all patients using combinations of chemotherapy.

Using 1980 data, we estimate that 45 percent of all cancer patients are curable. If we included patients with easily curable skin cancers and early cancers of the cervix, that figure rises to over 60%. In the 1960's the projected five year survival for patients with soft tissue sarcomas treated with surgery alone was only 40 percent. Now, with the addition of chemotherapy and surgery, the studies that were initiated in the mid 1970s demonstrate disease free survival in excess of 80 percent in some studies. Prior to the mid 1970s, no effective treatment was known for small cell lung cancer. Now with appropriate radiation therapy and chemotherapy, as many as 25 percent of patients with this disease are alive and well at two years after diagnosis.

These advances in cancer treatment have not come about by accident. They are the product of many years of hard work and of dedicated efforts on behalf of the private sector and of government. It must be emphasized that without the National Cancer Act,

without a coordinated, committed government effort, most of these advances which are now becoming evident would still be in the laboratory rather than at the bedside.

Before the National Cancer Act was passed there were fewer than 100 medical oncologists in the United States. Now there are more than 1,800 certified medical oncologists. There were only 77 full time radiation therapists. Now there are more than 1,400. The number of comprehensive cancer centers has grown from 3 in 1971 to 20 today. NCI supports an additional 41 specialized research centers which are geographically dispersed throughout the country and serve as local resources for conducting clinical trials and for information dissemination activities.

The legislative authorities, combined with the work of the cancer specialists at the community level and the work of the centers along with previously established clinical cooperative groups have made the concept of cancer control established in the first National Cancer Act a reality.

As part of this effort the NCI is discussing with oncologists around the country a concept for a hospital oncology program. It would provide for about 200 local centers to be established by community hospitals, clinics or a consortium of physicians. The goal of this project is to provide a way for getting practicing physicians and their patients into those national trials that have the highest priority. The exact role of federal support for the

program remains to be defined but is probably administrative in nature. This program is just an example of the kind of new and innovative thinking being done at NCI, at cancer centers around the country and by local physicians and oncologists to try to improve technology transfer.

None of this progress could have been made without federal money. Those of us in the medical profession know that the bulk of the monies available for cancer research come from the federal government and that there is no way those funds could be replaced by the private sector.

The American Cancer Society devotes over $100 million a year to cancer research, education and service programs. Last year the federal government devoted close to $1 billion to cancer research, control and technology transfer. ACS simply could not raise that kind of money in the private sector.

Although much has been done much more needs to be done. This year more than 400,000 will die of cancer. About 58 million Americans now living will eventually have cancer. Despite the advances in treatment and cure of childhood cancers, this disease still kills more children ages 3 to 14 than any other.

For the sake of the 835,000 people this year who will be diagnosed as having cancer, the special authorities, the commitment embodied in the National Cancer Act must be continued. Direct appointment by the President of the Director of the National Cancer

Institute and members of the National Cancer Advisory Board represents a personal Presidential involvement and commitment vital to the progress of the program. The same is true of the President's Cancer Panel.

In the original report on H.R.11302, the first National Cancer Act, the Congress found that direct appointment of the Director and the Board would "provide a degree of independence in management, planning, budget presentation and assessment of progress necessary to undertake a project of such magnitude as the attack on cancer." Nothing has happened in the intervening years to change the magnitude of the task and that degree of independence is still necessary.

The President's Cancer Panel was provided for because of "the impossiblity of the President to follow the progress of the attack on cancer on a day-to-day basis..." The direct oversight of the program was to be accomplished through this panel of highly qualified individuals. With very few exceptions that idea has worked.

In addition, and perhaps most importantly the budget by-pass provision must be continued and we are greatly disturbed that this legislation does not do that. It is most important that the budget for the National Cancer Institute, charged with overseeing research and prevention to combat this, the most feared disease in our nation, be presented to OMB and to the

President directly from the Director of the Institute. The need for the President to know precisely what the scientists and physicians charged with doing the direct work in treatment and prevention of cancer believe is necessary to do the best job possible is perhaps even more important in 1982 than it was in 1972 because of the necessary budget constraints and difficult fiscal decisions that must be made by the President and by Congress. Nothing in the legislation prohibits the Secretary of HHS or the Undersecretary for Health from providing comment and recommendation to the President.

In fact quite the opposite is true. The Secretary is specifically permitted to do just that and in recent years it is the Secretary's recommendation that has prevailed. Nonetheless, it is important that the President was provided with the budget figures that the scientific and medical communities thought were appropriate to do the job. I, as a physician feel better knowing that the decision that was finally made was, at least, informed.

The American Cancer Society Public Issues Committee passed a resolution on February 3 of this year supporting a $1.2 billion appropriation for NCI for fiscal year 1983. We did that because we believed that such an appropriation level would permit NCI to fully carry out the activities necessary to continue to make progress in treating and preventing cancer.

In its Citizens Budget for NCI in FY 1981, the American Cancer Society recommended $1.035 billion. We made the same recommendation in 1982. Although the Society has, over the years, consistently recommended a Citizens Budget for NCI which was in excess of the President's budget, the "no-increase" recommendation for FY 1982 was an attempt to respond to the growing financial pinch of the federal government.

However, recent data indicates that the impact of the cost of cancer on industry, labor, and the country continues to rise dramatically and alarmingly. It cost our nation between $13.7 and $17.1 billion in 1975 in loss of production and other indirect economic costs. The Third National Cancer Survey indicates that approximately $3.5 billion was spent in 1976 on hospital costs alone in treating cancer.

It is, in our estimation, tragically false economy to keep the investment in cancer research down as a "budget" matter, when it continues unrelentingly to increase the social, psychological, physical, and economic cost to the nation.

In recommending $1.2 billion, the Society believes that the NCI would be able to fully fund the requests of cancer centers for more money; would put off for at least one year, termination of the organ site programs; and would allow funding of a significant increase in the number of cancer research grants.

As I have detailed, much progress has been made in treating cancer and much needs to be done. There is no question that the 278,000 Americans now projected to get cancer this year and live beyond five years must be increased dramatically. At least 139,000 people with cancer will probably die in 1982 who might have been saved by earlier diagnosis and prompt treatment. The technology transfer strides that have been made in the last decade must continue if we are to avoid losing another 139,000 or more people in 1983 and in the years after.

We must continue what we have started. There are 3 million Americans alive today with a history of cancer. There is reason to believe that future developments in research areas we are now only beginning to explore will increase that number by many fold. However, we in the private sector cannot do it alone.

The explosion of biological knowledge in the past decade can be translated into clinical diagnosis and treatment in this decade if we continue on course. Here are just some of the areas now being explored by researchers and clinical oncologists:

- Scientists are working with biologic response modifiers, among them Interferon and Thymosin. Thymosin is produced by the thymus gland. A partially purified thymosin preparation called thymosin fraction 5 has shown promise when used with chemotherapy in significantly prolonging the survival of patients with oat cell carcinoma of the

lung, as well as head and neck tumors following radiation therapy.

- o "Monoclonal antibodies" are produced by a genetic fusing of cancer cells with disease fighting white blood cells. Monoclonal antibodies are specific antibodies tailored to seek out chosen targets such as cancer cells.
- o A series of chemical injections near the spine can act as a nerve block, relieving certain cancer patients of debilitating pain.
- o Retinoids, synthetic "cousins" of Vitamin A, have prevented bladder and breast cancers in mice and rats, and may also work against cancers of the lung, esophagus and pancreas in humans.
- o About fifty drugs have been found effective against certain cancers, and others that are still being tested hold promise.
- o Common demoninator approaches to cancer prevention may include the study and manipulation of "oncogenes" - cancer-causing genes which normally are dormant but which may be activated by radiation, chemicals and viruses. Researchers have learned how to suppress oncogenes in some animals, and are determining whether the same thing can be done in humans.

These are just some of the new areas of research in which scientists and physicians are working. It is up to all of us - those of us in the medical community and in the research community and you here representing us to our government - to make these possibilities translate into lifesaving realities. We are asking that you continue to help us fight cancer over the next decade as you have over the last decade. We all have reason to be proud of the achievements made in cancer treatment. We all have reason to lament that this progress is not nearly adequate to meet the problem. We cannot afford to find ourselves in this room ten years hence talking of what might have been, talking of the lives that were needlessly lost. We must move forward.

TESTIMONY

On Behalf

of

THE AMERICAN CANCER SOCIETY

Before

Health and Environment Subcommittee
of the Labor and Human Resources Committee
U.S. House of Representatives

SAUL GUSBERG, M.D.

Co-Chairman,
National Public Issues Committee
American Cancer Society

March 29, 1982

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TESTIMONY OF DR. SAUL GUSBERG

Mr. Chairman, members of the Committee, I am privileged to be here today representing the American Cancer Society, a voluntary health agency with over 2 million active volunteers. I am here to express the Society's strong support for a three year reauthoriation of the National Cancer Act and for an authorization level that will permit the National Cancer Institute and those of us who are practicing oncologists an opportunity to continue and to surpass the progress made during the last decade.

My present title is Distinguished Service Professor for the Mount Sinai School of Medicine and Consulting Gynocolgist and formerly Chief to the Mount Sinai Hospital in New York. In addition, I served as the Chairman of the Committee on Malignant Disease for the American College of Obstetricians and Gynecologists from 1966 to 1970. I am proud to have served as National President of the American Cancer Society in 1980 and was also formerly President of the Society of Gyncologic Oncologists, The Society of Pelvic Surgeons and the New York Academy of Medicine. I am here today as the co-chairman of the National Public Issues Committee of the American Cancer Society.

I know there are many who say that progress has not been made in cancer treatment and prevention. There are those who question the national cancer program and who question the resources we, as a nation have committed to that program.

I am here to say that the last decade has seen remarkable achievements in the treatment and prevention of cancer. This is especially true in childhood cancers, which while they may not be the most prevalent are certainly among the most heart rending.

In 1960 if one of your children or grandchildren had been diagnosed as havings acute lymphocytic leukemia that child would have had one chance in one hundred to live for 5 years. Today, a young leukemia patient's chances for 5-year survival are 50 percent and still improving. In fact, now more than half of all children with a variety of cancers can expect to live a normal life free of disease. Children with cancers of the bone and connective tissue, such as Ewing's sarcoma and rhabdomyosarcoma, once were cured only 10 to 20 percent of the time. Now, surgery, followed by local radiation therapy and chemotherapy to halt distant spread of cancer cells, can cure 60 to 70 percent of children. Surely, that statistic alone is worth whatever money we have spent to further research and treatment in this area.

In 1981 110,000 women were discovered to have breast cancer, (one American woman in 11 will develop breast cancer), and more than 37,000 women died of breast cancer. Today chemotherapy is used as a sequel to surgery or radiation therapy as well as in cases of recurrence or metastasis and

these drugs are beginning to boost survival rates that have been unchanged for 30 years. Although trends already are apparent, the statistics that reflect increased survival are expected to become even more dramatic in the next 5 to 10 years. This new hope for survival is coupled with innovations in reconstructive surgery and more often with less radical initial surgery making the disease less feared. Women are now more encouraged to do what is necessary to ensure early detection and are availing themselves with greater frequency of such detection techniques such as the use of mammography.

Hodgkin's disease, a lymph node cancer, is now curable in the overwhelming majority of patients due to the development and skillful use of radiation therapy and drug treatment. Over 80 percent of patients with localized disease are cured by radiotherapy while half of those with advanced disease involving the liver, bone marrow, lung, or other organs, are surviviing for long periods with combinations of drugs. There are, in addition, several other cancers of the lymphatic system which are now curable with radiation therapy and combinations of drugs. Diffuse histiocytic lymphoma, one of the most serious of these cancers, now can be cured in half of all patients using combinations of chemotherapy.

Using 1980 data, we estimate that 45 percent of all cancer patients are curable. If we included patients with easily

curable skin cancers and early cancers of the cervix, that figure rises to over 60%. In the 1960's the projected five year survival for patients with soft tissue sarcomas treated with surgery alone was only 40 percent. Now, with the addition of chemotherapy and surgery, the studies that were initiated in the mid-1970s demonstrate disease free survival in excess of 80 percent in some studies. Prior to the mid-1970s, no effective treatment was known for small cell lung cancer. Now with appropriate radiation therapy and chemotherapy, as many as 25 percent of patients with this disease are alive and well at two years after diagnosis.

These advances in cancer treatment have not come about by accident. They are the product of many years of hard work and of dedicated efforts on behalf of the private sector and of government. It must be emphasized that without the National Cancer Act, without a coordinated, committed government effort most of these advances which are now becoming evident would still be in the laboratory rather than at the bedside.

Before the National Cancer Act was passed there were fewer than 100 medical oncologists in the United States. Now there are more than 2,800 certified medical oncologists. There were only 77 fulltime radiation therapists. Now there are more than 1,400. The number of comprehensive cancer centers has grown from 3 in 1971 to 20 today. NCI supports an additional 41

specialized research centers which are geographically dispersed throughout the country and serve as local resources for conducting clinical trials and for information dissemination activities.

The legislative authorities, combined with the work of the cancer specialists at the community level and the work of the centers along with previously established clinical cooperative groups have made the concept of cancer control established in the first National Cancer Act a reality.

As part of this effort the NCI is discussing with oncologists around the country a concept for a hospital oncology program. It would provide for about 200 local centers to be established by community hospitals, clinics or a consortium of physicians. The goal of this project is to provide a way for getting practicing physicians and their patients into those national trials that have the highest priority. The exact role of federal support for the program remains to be defined but is probably administrative in nature. This program is just an example of the kind of new and innovative thinking being done at NCI, at cancer centers around the country and by local physicians and oncologists to try to improve technology transfer.

None of this progress could have been made without federal money. Those of us in the medical profession know that the

bulk of the monies available for cancer research come from the federal government and that there is no way those funds could be replaced by the private sector.

The American Cancer Society devotes over $100 million a year to cancer research, education and service programs. Last year the federal government devoted close to $1 billion to cancer research, control and technology transfer. ACS simply could not raise that kind of money in the private sector.

Although much has been done much more needs to be done. This year more than 400,000 Americans will die of cancer. About 58 million Americans now living will eventually have cancer. Despite the advances in treatment and cure of childhood cancers, this disease still kills more children ages 3 to 14 than any other.

For the sake of the 835,000 people this year who will be diagnosed as having cancer, the special authorities, the commitment embodied in the National Cancer Act must be continued. Direct appointment by the President of the Director of the National Cancer Institute and members of the National Cancer Advisory Board represents a personal Presidential involvement and commitment vital to the progress of the program. The same is true of the President's Cancer Panel.

In the original report on H.R. 11302, the first National Cancer Act, The Congress found that direct appointment of the

Director and the Board would "provide a degree of independence in management, planning, budget presentation and assessment of progress necessary to undertake a project of such magnitude as the attack on cancer." Nothing has happened in the intervening years to change the magnitude of the task and that degree of independence is still necessary.

The President's Cancer Panel was provided for because of "the impossibility of the President to follow the progress of the attack on cancer on a day-to-day basis..." The direct oversight of the program was to be accomplished through this panel of highly qualified individuals. With very few exceptions that idea has worked.

In addition, and perhaps most importantly the budget by-pass provision must be continued and we are gratified that this legislation does that. It is most important that the budget for the National Cancer Institute, charged with overseeing research and prevention to combat this, the most feared disease in our nation, be presented to OMB and to the President directly from the Director of the Institute. The need for the President to know precisely what the scientists and physicians charged with doing the direct work in treatment and prevention of cancer believe is necessary to do the best job possible is perhaps even more important in 1982 than it was in 1972 because of the necessary budget constraints and

difficult fiscal decisions that must be made by the President and by Congress. Nothing in the legislation prohibits the Secretary of HHS or the Undersecretary for Health from providing comment and recommendations to the President.

In fact quite the opposite is true. The Secretary is specifically permitted to do just that and in recent years it is the Secretary's recommendation that has prevailed. Nonetheless, it is important that the President was provided with the budget figures that the scientific and medical communities thought were appropriate to do the job. I, as a physician feel better knowing that the decision that was finally made was, at least, informed.

The American Cancer Society Public Issues Committee, of which I am co-chairman, passed a resolution on February 3 of this year supporting a $1.2 billion dollar appropriation for NCI for fiscal year 1983. We did that because we believed that such an appropriation level would permit NCI to fully carry out the activities necessary to continue to make progress in treating and preventing cancer.

In its Citizens Budget for NCI in FY 1981, the American Cancer Society recommended $1.035 billion. We made the same recommendation in 1982. Although the Society has, over the years, consistently recommended a Citizens Budget for NCI which was in excess of the President's budget, the "no-increase"

recommendation for FY 82 was an attempt to respond to the growing financial pinch of the federal government.

However, recent data indicates that the impact of the cost of cancer on industry, labor, and the country continues to rise dramatically and alarmingly. It cost our nation between $13.7 and $17.1 million in 1975 in loss of production and other indirect economic costs. The Third National Cancer Survey indicates that approximately $3.5 billion was spent in 1976 on hospital costs alone in treating cancer.

It is, in our estimation, tragically false economy to keep the investment in cancer research down as a "budget" matter, when it continues unrelentingly to increase the social, psychological, physical, and economic cost to the nation.

In recommending $1.2 billion, the Society believes that the NCI would be able to fully fund the requests of cancer centers for more money; would put off for at least one year, termination of the organ site programs; and would allow funding of a significant increase in the number of cancer research grants.

The request in H.R. 5919 is in line with a realistic view of the needs of the cancer program and we support both the authorization level and the maintance of the special authorities which I have outlined.

As I have detailed, much progress has been made in treating cancer and much needs to be done. There is no question that

the 278,000 Americans now projected to get cancer this year and live beyond five years must be increased dramatically. At least 139,000 people with cancer will probably die in 1982 who might have been saved by earlier diagnosis and prompt treatment. The technology transfer strides that have been made in the last decade must continue if we are to avoid losing another 139,000 or more people in 1983 and in the years after.

We must continue what we have started. There are 3 million Americans alive today with a history of cancer. There is reason to believe that future developments in research areas we are now only beginning to explore will increase that number by many fold. However, we in the private sector cannot do it alone.

The explosion of biological knowledge in the past decade can be translated into clinical diagnosis and treatment in this decade if we continue on course. Here are just some of the areas now being explored by researchers and clinical oncologists:

- Scientists are working with biologic response modifiers, among them Interferon and Thymosin. Thymosin is produced by the thymus gland. A partially purified thymosin preparation called thymosin fraction 5 has shown promise when used with chemotherapy in significantly prolonging the survival of patients with

oat cell carcinoma of the lung, as well as head and neck tumors following radiation therapy.

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- A series of chemical injections near the spine can act as a nerve block, relieving certain cancer patients of debilitating pain.
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These are just some of the new areas of research in which scientists and physicians are working. It is up to all of us - those of us in the medical community and in the research community and you here representing us to our government - to make these possibilities translate into lifesaving realities. We are asking that you continue to help us fight cancer over the next decade as you have over the last decade. We all have reason to be proud of the achievements made in cancer treatment. We all have reason to lament that this progress is not nearly adequate to meet the problem. We cannot afford to find ourselves in this room ten years hence talking of what might have been, talking of the lives that were needlessly lost. We must move forward.

Testimony

For the Record

of the

Association of American Cancer Institutes

before the

Committee on Labor and Human Resources

United States Senate

on the

"Biomedical Research, Training, and

Medical Library Assistance Amendments of 1982"

Presented by

Dr. Timothy R. Talbot, Jr.

Vice Chairman of the Board and former President

Fox Chase Cancer Center

Philadelphia, Pennsylvania

and

President, Association of American Cancer Institutes

AUTHORIZATION TESTIMONY

It is a pleasure and a privilege for us to present to you the views of the Association of American Cancer Institutes (AACI) regarding the authorizations and programs of the National Cancer Institute for the fiscal year of 1983, and following.

I am Dr. Timothy R. Talbot, Jr., Vice Chairman of the Board, and until recently the President of the Fox Chase Cancer Center in Philadelphia, and the current President of the AACI. I am also one of the founding members of that Association, which was formed in 1958 for the purpose of improving cooperation and exchange of information among cancer centers and the National Cancer Institute; and to work together for the encouragement of programs that will improve the National effort against cancer. Dr. Kenneth Endicott, who was then the Director of NCI, encouraged this relationship as one of the many examples of his leadership.

The membership of the AACI is composed of the chief executive officers, or their representatives, of about 65 cancer centers, including the 20 comprehensive cancer centers. Each of these comprehensive centers, which are recognized by the NCI, conducts programs in basic cancer research, research in patient treatment and diagnosis, and programs of community outreach. The other centers are also important, but less diversified, institutions devoted to either basic cancer research or clinical research, or both. Together these centers constitute a major resource and force in the nation for all of the programs fostered and

supported by the NCI. A very large proportion of the important innovative research about cancer is conducted within these 65 cancer centers.

We are pleased to note that the formal statement of the Director of NCI, in his presentation before the House Subcommittee on Labor-HHS Appropriations, stated that: "The Cancer Centers Program provides support for clinical and basic laboratory research through comprehensive cancer centers and specialized centers distributed throughout the nation. These centers promote a coordinated national effort on research in cancer related fields. Efforts include basic research in cancer biology, clinical research, and transfer of new knowledge to physicians in communities."

It is especially our wish to express our thanks to this Committee for all of their support of the cancer program during the last two or more decades. This support preceded the passage of the National Cancer Act, and thus in an important way also coincides with the aims and objectives of the AACI, which go back as far as 1958. This Committee and our Association, therefore, share at least twenty years of a common concern.

We also wish to express our recognition of our National economic circumstances. We are cognizant of the necessity to "gird up our loins." We believe that benefit can result from a continual re-examination of our goals and objectives, with a concomitant examination of priorities and careful attention to a balanced relationship of expenditures to priorities. We have done our best, in our proposals, to balance the welfare of the nation with our current economic realities.

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This Committee has heard, during each year of the last two or more decades, an accounting of the advances that have been made during each of those years. Progress against ignorance is slowly achieved. More often than not, there is a gap of many years between each new understanding of biology and our ability to translate it into patient care. Cancer is just one part of the complex processes of Nature--but we are steadily gaining in our understanding of these processes. Great and exciting progress has been made during the last few years, and this offers great promise for the future--far greater promise than mankind ever dreamt of before.

ADVANCES IN RESEARCH

Advances made during the last 10 years are described in the attached extract of a report prepared by Dr. Gerald Murphy, Director of the Roswell Park Memorial Institute, in May of 1981. This was based on a survey of all cancer centers in the nation.

Progress during the most recent year is also exciting, but the Committee must be aware that what has become visible, or recognized, during the past year has in almost all cases been the result of a decade or more of work that was in progress before it became visible or accepted. A few examples follow:

1. Hybridoma Research and Technology -- This has huge implications in all of the areas of diagnosis, treatment and the understanding of the entire field of cancer and biology. This includes the vast explosion of technology and knowledge about monoclonal antibodies in all of the areas mentioned above.

2. Prevention -- Many aspects of modern biochemistry and biology provide new clues to this complex field. So far, however, the greatest preventable cancer, lung cancer, has resisted societal and political circumstances because of the cigarette issue.

3. Cancer of the Liver -- Here we refer to cancer of the liver that originates in the liver, which is, therefore, called primary cancer of the liver. This is now known to be associated with the hepatitis B virus. Dr. Baruch S. Blumberg of the Fox Chase Cancer Center was awarded the Nobel Prize for his work which demonstrated the relationship of the hepatitis B virus to primary cancer of the liver. This also led to the development of a vaccine against hepatitis B. Although not common in the United States, primary cancer of the liver is the most common cause of death in other parts of the world, including Africa and China. Thus, the way is now open, with appropriate public health assistance and measures, to the prevention of one of the most common cancers in the world. It may be that this will lead to other similar understandings of the causes of cancer, but it is too soon to promise this.

4. Genetics and Cancer -- There has been a recent explosion of knowledge in this area. This is an extremely interesting and an important area, and much of the new information has emerged from cancer centers. This includes the fields of chromosomes and cancer, oncogenes, the relationship of genetics to the environment, and many interacting variables among these factors.

The above four examples are only a small segment of the advances of the past year. Each of the above examples has great implications for both

diagnosis and treatment, since each contributes to our ability to define in detail the nature of each type of cancer and its response to treatment.

Other advances in biology have been made, which presage the potential of practical application. These range from characterization of immunological characteristics of various cell types in cancer and other diseases, to the reversibility of malignancy of terato-carcinoma in animals.

We are only beginning to realize the potential of these new advances in biomedical and cancer research. At the same time, we are continuing to develop better ways of taking care of the patients with cancer, both humanely and scientifically. But we are painfully aware that we are still at the threshold of where we hope to be. Because of this awareness, we believe that we must not allow our efforts to be diminished. We are dedicated to intelligent efforts, to a search for knowledge, to sensible priorities, and to fiscal responsibility and accountability. But those of us who have spent a lifetime in the pursuit of progress against cancer--and other diseases--find it hard to believe that we should retrench when the most exciting era of potential advances is before us.

RECOMMENDATIONS

We have a number of recommendations to make to this Committee regarding funding for the NCI. We have appended to this testimony, and we request that it be made part of the record, the complete list of recommendations we make, all of which are described in the document which is titled, "Association of American Cancer Institutes - Recommendations for National Cancer Act Renewal."

1. Cancer Centers: Cancer centers are supported by grants known as Cancer Center Support Grants, also known as "core grants." For every four dollars of research grants (R-01 and P-01), there is now approximately one dollar in the cancer center support grants which have often been described as the "glue that holds a center together." This ratio has been decreasing slowly but steadily during the last few years (see accompanying graph and Table 1).

   We would like to report to you that the authorizing committee in the House has already begun steps to improve this situation. In the bill introduced by Mr. Waxman on March 22, 1982, HR 5919, the "Health Research Act of 1982," there is created a specific authorization for cancer center support grants. We note with pleasure that the bill establishes the authorization levels of $83,000,000 for fiscal year ending September 30, 1983; $93,000,000 for fiscal year ending 1984; and $103,000,000 for fiscal year ending 1985. This is a step in the right direction.

   We hope that this proposed specific authorization will be included in the final authorization legislation as it emerges from the Congress.

2. Centralized Patient Data System: We are pleased to note that in the NCI presentation to your committee, the statement is made that "support will continue for the Centralized Cancer Patient Data System" and we urge that this policy be given support by bill report language. Recent information leads us to question whether or not this long-term commitment of the NCI will be fulfilled.

3. 10% Cut in Indirect Costs: We note with alarm that there has been an Administration proposal that the indirect cost rate on research grants be reduced by 10%. This could have only one result, which would be an unjust and imbalanced reduction of biomedical research in the nation. It should also be pointed out that this is an ineffective way to effect cost savings. The indirect cost rate of every institution is individually determined, on the basis of individual needs of each institution, and individual accounting. To deal with such a complex array of diversity with a single "uniform" formula will result in a remarkable lack of uniformity of consequences.

4. We believe that the existing narrow definitions of eligibility for appointment to the National Cancer Advisory Board should be considerably widened, and refer you to our recommendation, attached, in this regard.

5. There are some additional recommendations, in the attached document. We will be pleased to work with you and your staff to meld them into your bill, if you find this to be desirable or helpful.

Thank you for permitting us to give our views. We will be pleased to answer any questions that you may have and to work with you and your staff whenever it is believed that we may be helpful.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Assistant Secretary
for Health
Washington DC 20201

MAY 25 1982

The Honorable Orrin G. Hatch
Chairman, Committee on Labor
and Human Resources
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

Thank you for sending me Senator Hawkins' followup questions from my testimony before the Labor and Human Resources Committee on March 31, 1982. Enclosed please find my response.

If I can be of further assistance, please let me know.

Sincerely yours,

Edward N. Brandt, Jr., M.D.
Assistant Secretary for Health

Enclosures

Questions from Senator Hawkins

Question I.

Dr. Brandt, I was very impressed with your willingness to correct the problems and deficiencies that were addressed at the Oversight hearings. I hope that the Task Force's recommendations are considered and carried out by the National Institutes of Health.

How optimistic or pessimistic are you concerning the ability of the NCI to correct these deficiencies through administrative action?

Answer

I should first point out that, although the Task Force on NCI-FDA Investigational New Drugs made a number of recommendations, these did not necessarily represent problems or deficiencies in the National Cancer Institute's operations. Furthermore, many of the areas identified through the recommendations are areas in which the NCI already has made changes. Implementation of the bulk of the 31 recommendations that specifically apply to the NCI are in process and the progress that we are making in this effort will be reported to Senator Hawkins in the near future. The Institute is in the process of implementing the additional five recommendations. I believe that the recent intense scrutiny of the Drug Development Program by the Task Force has shown that NCI management has made major improvements in managing this program over the past eight years, and that the existing procedures provide a high degree of protection for patients entering clinical trials while assuring the rapid assessement of new drugs. I am more than optimistic that the NCI is being responsive to the Task Force recommendations and that the Institute will continue to make further changes, when necessary, to assure the safety and productivity of this system.

For your information, I will comment on two of the recommendations that merit particular attention.

The Task Force made recommendations relating to the need for continued review and evaluation of the new NCIU Toxicology Protocol. This protocol is under continuing review by the NCI and, in fact, a progress report on the utility of the protocol was presented on May 7, 1982, to the FDA's Oncologic Drugs Advisory Committee. I should point out that the first three drugs tested under the new protocol have now entered Phase I trials, and no problems have arisen - the predicted starting doses were completely safe.

With regard to improved control and monitoring of clinical trials, the NCI already has taken several actions. They have instructed all recipients of clinical drugs that they must maintain a log of such drugs and be accountable for their dissemination. This should decrease substantially the "leakage" of drugs to unauthorized physicians. Second, the NCI now reports possible adverse drug reactions to the FDA on almost a daily basis and keeps the FDA informed continually on further actions taken. Third, working staff of the NCI's Division of Cancer Treatment and FDA's Division of Oncology and Radiopharmaceuticals are meeting regularly to resolve operational problems and [illegible] on details of reporting procedures, etc. Finally, the NCI has initiated a major expansion in its clinical monitoring program through an extensive system of site visits to its clinical investigators in order to insure the accuracy and validity of data generated and compliance with its rules and regulations.

Question 2.

Dr. Brandt, you are nationally recognized not only for your well-known administrative work as the Vice Chancellor for Health Affairs of the University of Texas, but also for your expertise in family practice and community medicine. Since you have come to Washington, have you had an opportunity to explore the community work of the National Cancer Institute and if so, have you found any outstanding work, or have you suggested any new departures?

Answer

Involvement of community participants by the National Cancer Institute has been primarily through educational and cancer control initiatives, attempting to access both lay and professional groups. An example of an initiative that has evolved out of the Institute's excellent community efforts is the program entitled, "Community Cancer Oncology Program" (CCOPS). This program, expected to be announced early this summer, will involve community efforts in cancer control, with the first portion of the program encouraging community physicians to participate in clinical research activities. Community physicians will work with regional cancer centers and/or national cooperative groups by placing patients on protocol studies. This approach is a reflection of our belief that the best way to teach is through personal involvement. Research awards will be made to community physicians who have demonstrated an interest in developing local prevention programs and in the early detection of cancer as well as an interest in supportive and rehabilitative care for patients with cancer.

Communities receiving research support also will participate in future cancer control activities, particularly in primary prevention programs. The CCOPS effort is different from previous NCI community outreach activities in that the administrative focus and the financial awards will be centered in the communities themselves. Previous community networks which interacted with centers and cooperative groups were a subordinate extension of those operations, and also were finite in lifespan because most of them were supported by a contract mechanism. The CCOPS program will allow for greater participatory responsibility by the communities and will not be time-limited. I believe that a major benefit of this new NCI program will be the continual enhancement of cancer expertise in communities across the country.

Question 3.

In the National Cancer Program's published plan for fiscal years 1980-1982, there is the statement that occupational studies of populations exposed to specific occupational carcinogens or suspected carcinogens will be expanded. The emphasis was put on lung cancer particularly in Southern U.S. coastal areas. Could you tell us if this important expansion is taking place?

Answer

The National Cancer Institute, through its Field Studies and Statistics Program, has expanded its efforts in the occupational area. Additional research staff and resources are being devoted to investigations of the health experience of occupational groups who may come in contact with known or suspect carcinogens while at work.

Evaluation of geographic patterns of lung cancer from the Atlas of Cancer Mortality for U.S. Counties revealed "hot spots" where mortality was excessive in coastal areas of the southern U.S., a finding which suggested exposures from previous employment in shipyards might be involved. NCI case-control studies of lung cancer in these areas have confirmed this suspicion. In addition, other unusual geographic patterns for leukemia, lymphoma, and cancers of the bladder, colon, and liver led to the initiation of case-control studies to evaluate the role of occupational and other factors in the origin of these tumors.

The Field Studies and Statistics Program also is conducting approximately 40 other epidemiologic studies of occupational groups. These studies include groups exposed to pesticides, solvents, welding fumes, asbestos, talc, dry cleaning fluids, and wood dusts. The NCI recently initiated a series of crucially important studies to evaluate the cancer experience of such occupational groups as embalmers, anatomists, plywood manufacturers, chemical workers, resin manufacturers, and photographic film producers who are exposed to formaldehyde, a substance recently shown to cause nasal cancer in laboratory animals.

Question 4.

What do you think the family physician and the community physician can do to better serve high risk populations cited by the National Cancer Institute? Should the government be beaming some action program to them? Is the NCI or some other HHS agency doing that?

Answer

I agree that we must make every effort to better serve high risk populations and that family and community physicians have an important role to play. High risk populations normally include individuals from lower socioeconomic classes, environments in which individuals frequently are heavy smokers, suffer from poor dietary habits, and often are exposed to environmental toxins (usually occupational). Although educational efforts have accomplished some changes in attitudes among these high risk groups, behavioral improvement (elimination of adverse "lifestyle" situatio and of economic and educational disadvantages) has been more limited. Family and community physicians exercise a vital role in patient education, but they operate within a local social environment that can be difficult and slow to change.

The Federal Government along with many other organizations, supports professional education programs directed toward family and community physicians in an attempt to increase their understanding of the importance of personal lifestyles; however, the methodology for changing group and individual behavior requires more work. I believe that educational programs coupled with research aimed at developing a greater understanding of successful approaches to modifying behavior where dramatic improvement in socioeconomic status is not likely, is our best hope for reducing risk factors for certain population subgroups. Family and community physicians are an integral part ot any of our health promotion activities and are crucial to the achievement of any success.

Question: Last year $2 million was restored to the MBRS budget. Why is this not reflected in the FY 1983 budget?

Answer: The Division of Research Resources (DRR) actually obligated $18,857,000 in the Minority Biomedical Research Support Program in 1981. The Administration had proposed a $2 million rescission in 1981 which reduced the level to $16.8 million. Congressional action on this proposed rescission in June 1981 restored the $2 million, raising the 1981 funding level back up to $18,857,000. However, the current 1982 level of $18,065,000 was derived from the President's 1981 proposed rescission level of $16.8 million, which did not reflect the restored $2 million. Additionally, a 4 percent reduction was imposed on all activities as a result of the third Continuing Resolution for 1982, that further reduced each appropriation by 4 percent.

The 1983 President's Budget request of $18,508,000 was derived from this 1982 Continuing Resolution level of $18,065,000, an increase of $443,000, or 2.5 percent over the 1982 level. In light of current budget constraints and the many competing demands for the Federal dollar, the 2.5 percent increase for MBRS appears equitable.

Question: There will be 68 grant awards in FY 1983, reflecting a loss of 12. Does this indicate a retrenchment in the Program's scope and objectives?

Answer: DRR is still very much committed to this Program and does not anticipate any major changes in the Program's scope or objectives. Increases in the cost of doing research make it difficult to support more than the 68 grants reflected in the 1983 request. It is expected that, through attrition, some of the projects currently receiving support will no longer require support in 1983. Nevertheless, as a result of increased research costs, DRR will only be able to support those noncompeting and competing renewal applications that receive the highest priority scores in their peer review. DRR does not plan to support any new awards within the 1983 budget.

Question: Did the minority institutions stop applying for these funds?

Answer: No, most of the institutions are still applying to receive a portion of the MBRS funds. In addition, some of these institutions are also applying for, and receiving, research project grant support from the categorical institutes, Minority Access to Research Careers (MARC) support from the National Institute of General Medical Sciences (NIGMS), and Biomedical Research Support Grants (BRSG) from DRR.

Question: Are there any approved, unfunded grants?

Answer. Yes. After the February 1982 National Advisory Research Resources Council meeting, DRR had 18 approved unfunded MBRS applications in-house at a total cost of approximately $2.8 million. Seventeen of these 18 applications had priority scores ranging from 170 to 271 with the eighteenth priority score at 345. Thirteen of the applications were competing supplementals, one was a competing renewal, and four were new applications.

Question: How much money will be necessary to keep the level of funding at 80 grants?

Answer: It would take approximately $3.3 million additional in 1983 to maintain the MBRS Program at a level of funding enabling support to 80 institutions.

Question: Has the MBRS Program met its goals?

Answer: The overall goal of the MBRS Program is to increase the number of minority scientists engaged in biomedical research. While an absolute measure towards attaining this goal must await a comprehensive evaluation of the MBRS Program, there are indications that it is being successful. For example, there have been nearly 4,600 minority students who have graduated from institutions with MBRS Programs. About 50 percent of these students have gone on to pursue advanced degrees in health professions. Another 40 percent have gone primarily to graduate school to pursue the Ph.D. degree in biomedical sciences. Most of the others have entered health science careers at the paraprofessional level.

The MBRS Program has been successful enough in improving the research capabilities of minority institutions that eight institutions participating in the Program have entered the mainstream of biomedical research with investigators successfully competing for, and receiving, research project grant support. In addition, 14 MBRS institutions have been successful enough in their research endeavors to attain Biomedical Research Support Grant eligibility.

As a result of the scientific excellence achieved by MBRS participants in recent years, it had been suggested that the name of the Program be changed to the Minority Biomedical Research Support Program. The addition of the word "Research" in the title is to recognize the fact that the Program has evolved to the point that significantly high quality research is being conducted. This name change has been made official, and now provides a much more accurate description of the Program's activities.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20205

MAY 14 1982

The Honorable Orrin G. Hatch
Chairman, Committee on Labor
and Human Resources
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

Thank you for sending me the follow-up questions that Senator Hawkins has posed as a result of my testimony before the Labor and Human Resources Committee on March 31, 1982. I appreciated the opportunity to testify before this committee and am pleased to respond to the Senator's questions.

We have numbered the questions and where the content of several questions is related, have provided a common answer.

If I can be of further assistance, please let me know.

Sincerely yours,

Jane E. Henney M.D. for

Vincent T. DeVita, Jr., M.D.
Director
National Cancer Institute

Enclosure

Questions from Senator Hawkins

Question 1.

You mentioned at a recent cancer board meeting that your Institute had started more new programs under your leadership, in a time when the budget was rather stable, than at any earlier time in its history. I want to compliment you on this. Could you please tell me what those new programs are?

Answer

The new efforts that have recently been initiated include:

- Chemoprevention Program - this program takes advantage of the fact that certain substances can prevent the formation of cancer in animals exposed to cancer-causing agents.

- Community Clinical Oncology Program - this program will establish the link between community hospitals, cancer centers and the large cooperative groups conducting our clinical treatment research.

- Biological Response Modifiers Program - a program which does research on substances, known as biological response modifiers, that boost, direct or restore the body's natural defenses against cancer.

- Radiation Research Program - a consolidation of radiation efforts on low-level radiation, radiation therapy and diagnostic imaging.

- Cancer Causation - a new emphasis of the research goals in applied prevention to find ways to interfere with the promotion stage of cancer causation.

- Cancer Control Research Units - to plan and implement cancer control research for a defined population.

Question 2.

The Committee has been told that you reviewed each and every NCI contract shortly after you became acting director. The implication was that you curtailed or eliminated about $35 to $50 million worth of contractual work. Which was it, $35 million or $50 million?

Answer

The analysis of the National Cancer Institute's contracts helped identify $40 million of activities that could be reduced or eliminated in Fiscal Years 1980 and 1981.

Question 3.

How was this economizing put to work? How did you spend that money?

Answer

The savings identified were redistributed to the new programs that were being initiated and to increase support of investigator-initiated research through project grants.

Questions 4,5,6,7.

4. If you had 50% more money to spend how would you spend it?
5. In the case of each of these items, has the board discussed them recently, and if so, what kind of priority did each of them get in general terms?
6. Have you asked for money to pursue this work?
7. In each case, can you tell us who originated the idea for the new effort?

Answer

I feel that the budget requested by the President is sufficient for us to honor our commitments and carry out our program plans.

Question 8.

Do you always follow the board's advice? Or do you sometimes find it necessary to go a different way than the board suggests?

Answer

There are, of course, occasions on which the determination is made not to follow the Board's advice. Although the Board's role is in most cases only advisory, we are seriously attentive to their recommendations and actively seek to involve them in all major decisions. And, we try to avail the Board of as much programmatic and fiscal information as possible, even though quite often that information does not, and cannot, adequately address all the parameters which must be considered in the day-to-day management of the National Cancer Program. Similarly, matters which require an immediate response, based on developments which have occurred subsequent to the Board's most recent considerations, may dictate an action by the Institute which reflects the most timely judgment of the NCI Directorate and which consequently may mandate an action which goes counter to the Board's advice. In either case, we would immediately inform the Board of the action which was taken and of the rationale for having pursued a course of action opposed to that which they had recommended.

Question 9.

Can you cite instances where you've had to depart from board advice?

Answer

In the almost 2 1/2 years during which I have been Acting Director and Director of the NCI, I cannot recall any instance in which I have had to depart from National Cancer Advisory Board advice on any major program, policy or budget issue. I think that this situation has pertained because I have considered the establishment and maintenance of a close working partnership with the NCAB as one of the most important aspects of my position as Director. The Board and the several subcommittees have participated from the very beginning in the discussion and formulation of major program policy, and budget issues. This full participation has provided for the resolution of any differences as they are identified - so by the time positions on major issues are finalized, the NCAB and the NCI are in agreement.

Questions 10 and 16.

10. Recently, Dr. Harold Amos was recorded as saying at a board meeting that he thought it was board members' duty to look into details on proposed notices, Requests for Applications, but as the meeting went on he took the option of passing up the chance to look at RFA details so that his institution, Harvard, could send in an application. Do you see this conflict of interest coming up often?

16. Until you had a legal opinion to the contrary just recently, you took the position that board members wanting to apply for applications in programs rather closely prepared by the board, itself, had to choose one way or the other, either help the board prepare the application criteria and give up the chance to apply, or step aside in designing the program in order to apply after the rest of the board set the criteria. Whatever the outcome of that discussion, how would you characterize the conflicts or interest on the board now?

Answer

Regarding the matter of having specific details of a Request for Application (RFA) provided to or even reviewed by members of an advisory board previous to its publication, the putative conflicts of interest which was raised as an issue of concern by Dr. Amos would admittedly be implicit, rather than actual. There are, as you point out, no legal strictures which currently mandate against such involvement, per se, provided the rest of the potential applicant community is afforded adequate time to prepare applications in response to the announcement and provided the input by the Board or its members does not result in the inclusion of selective or evaluative parameters which might afford an unfair advantage to the Board member or his institutional colleagues.

The specific RFA in question dealt with a highly publicized, controversial new program, the various elements of which represent the vested interests of many groups within the oncology community. In this case, it was felt that an absolute minimum of Board involvement in the preparation of the RFA would be the most circumspect and the most defensible posture. In general, however, seldom is an advisory council or board involved at all in the preparation of documents of this nature; the likelihood of this type of "conflict of interest coming up often" is therefore extremely remote.

Questions 11,12,14.

11. The composition of the board in January started with the Chairman, a director of a university cancer laboratory, then alphabetically went to a university professor of biochemistry, a university professor of microbiology and molecular genetics and, according to NCI's listing, eight other university professors. I know that we need expertise on the board, but do you think that there is this expertise available from industry or from foundations where members would not have so uniform an interest in protecting universities? After all, that's eight board positions out of 18, or 44% of the board.

12. I saw that 2 out of 18 board members are people from hospitals where the university affiliation is not listed; that's 11%. Do you think the board might be more patient oriented if there were more persons representing medical practice as members?

14. Do you think that the Senate's almost unanimous vote to encourage more small business participation in federally funded biomedical research might be served by putting more people from industry on the board?

Answer

As you know, the National Cancer Act specifically requires that the 12 scientist members of the NCAB be expert in the full range of biomedical disciplines of concern to this Institute and that among these may be medical doctors as well as investigative researchers. Undeniably, appropriate scientific expertise in those categories required to be represented on the NCAB could be obtained from private industry or from non-profit foundations rather than exclusively from academic institutions. And, to the extent that such Board members might be expected to communicate to the industrial community the objectives and initiatives of the National Cancer Program, it might well be anticipated that increased participation by private industry would result. Certainly, it is our intention that such representation be ultimately obtained, but by law it cannot be at the sacrifice of the mandated requirements for practicing clinical oncologists (at least two) or individuals expert in carcinogenesis (at least five). Now that our grant-in-aid mechanism applies to private industrial applicants

as well as to the university community, we are actively seeking to identify appropriate private sector representatives for our advisory boards and committees and will continue to do so.

With regard to your question regarding medical practitioners, the Cancer Act stipulates that the Board shall contain up to twelve medical doctors. At present, the distribution, in the categories to which you have referred, is shown in the table below. You might note that on the proposed slate of new members (to be effective 3/9/82) one of our present lay members whose affiliation is with a university is being replaced by a nominee from the public sectors; that the number of medical doctors is increased from 9 to 11 (50% to 61%); and that medical practitioners with specific patient care responsibilities will increase from the present 5 (28%) to 7 (39%) on the proposed NCAB.

DISTRIBUTION OF BOARD MEMBERS	PRESENT NCAB (%)	PROPOSED NCAB (%)
Lay members	6	6
Members with expertise in carcinogenesis	5	5
Medical Practitioners	9 (50)	11 (61)
Clinical oncology, patient care	5 (28)	7 (39)
Members with university affiliation	11 (61)	10 (55)

Question 13.

Every now and then there are standees at the board meetings, spectators. And the board table is possibly 30 feet long. You list, including ex-officios, totals 32 board members. Are the meetings compact enough so that the interchange among members is close and spontaneous?

Answer

Usually, the physical arrangement of Board members and senior NCI staff around the meeting table reflects our attempt to encourage just the sort of active interchange to which you refer. The ex officio and liaison members are statutory but non-voting members, and generally we seat them at the extremes of the "30 foot long" oval which serves as our conference table. And, because the better part of Board meetings is open to the public, we do have some standees in even our largest conference room. We try to provide overflow facilities for the use of visitors and interested observers who are not actually involved in NCAB proceedings. Nonetheless, as you have noted, it is a large group, but we do try to achieve a reasonable proximity of and maximal interaction between "working members" of the Board during meeting sessions.

Question 15.

I note that you now have a member employed by a trade union, a legal counsel, a newspaper columnist, a medical writer on your board. Have you found the presence of these nonscientists hampering the board's functioning? There are, of course, other nonscientists on the board.

Answer

Nonscientists have played an important role in the NCAB since its establishment by the National Cancer Act of 1971. Contrary to hampering the functioning of the Board, these members have contributed in a most productive and effective manner to Board operations, in general, and have assumed leadership of special subcommittees of the Board; the most recent example being the special committee appointed to advise the Director on the important and complicated recompetition of the contract for the operation of the Frederick Cancer Research Facility.

Since not all issues that come before the Board are scientific in nature but also include administrative and managerial issues, the nonscientific members have brought a special perspective and understanding of these issues which has served to supplement and complement the scientific viewpoints and have helped achieve a truer balance in Board deliberations.

Question 17.

Dr. DeVita, a committee of the board last autumn was assigned to look into the Organ Site Program. At that time the committee voted to support the organ site concept and went further. The committee voted that there should be other organ site task forces. The committee said that there were several organ sites, possibly brain, head and neck, and others. Specifically, the committee recommended that the next organ site task force should address cancer of the respiratory tract, including lung. I know that the entire board vote on this is yet to come, but what is your opinion on organ sites?

Answer

The organ site task forces have been successful in carrying out a major part of the mandates they were given 10 years ago. After a decade of stimulation some of these targeted organ site areas have been greatly stimulated and now have a thriving community of scientists pursuing research in these areas. Some other areas like brain, head and neck or respiratory tract may very well need some additional stimulation. The organ site concept is still a useful one but in order to maximize recent research developments and to meet current patient needs, more flexibility is needed in these programs. Various committees of the Board have proposed that these programs be restructured and modernized in order to increase their flexibility in dealing with areas that may need more attention and to make them more cost-effective given the current budgetary restraint. It should be noted that in FY'81, in addition to the approximately $23 million of research supported by the five organ site projects, approximately $47 million of research in the five sites was supported through contracts and grants. As you have noted, there will be a full NCAB discussion of their issue later this month and their recommendations concerning the restructuring and targetting of these programs will be valuable.

Question 18.

You stated earlier that you take very seriously the advice of the board. The Organ Site Program has been reviewed by the board at least five and possibly ten times since organ site task forces were formed. Each review has been favorable. Isn't there some conflict in your testimony that you respect the board's opinion but, in the face of five or ten approvals, you persist in phasing out organ site task forces?

Answer

While the reviews have been generally favorable, they have also uncovered a number of weaknesses in the program. There is no conflict between NCAB recommendations and NCI actions since the organ site programs are not being phased out, but some organ site research may be converted to other appropriate mechanisms of support. There are no significant differences between the Board and NCI staff. The only major issue to be resolved is the structure and location of the coordinating office.

Question 19.

The history seems clear that there was little progress against prostate cancer for 40 years. Now we have directly out of the Prostate Cancer Task Force an updated elucidation of the anatomy of prostate cancer, and we have new regimens that seem to be well on their way to putting prostate cancer side by side with childhood leukemia, osteogenic sarcoma, and other cancers which have been substantially reduced as death threats in recent years. Wouldn't you say that the prostate task force has performed admirably?

Answer

The National Prostatic Cancer Project with its chartered committee of scientist advisors has implemented a multidisciplinary research program encompassing the areas of etiology and epidemiology, detection and diagnosis, and treatment. The Project has been successful in stimulating and focusing research on prostatic carcinoma, a previously neglected area of cancer research. Through its Treatment Subgroup, the Project is conducting clinical cooperative trials to determine the usefulness of chemotherapeutic agents, singly or in combination with hormonal or other chemotherapeutic agents, and as adjuvant chemotherapy to surgery or irradiation. In general, these trials have demonstrated slight benefit in terms of prolongation of disease control and survival with Cytoxan and Estracyt and secondarily with 5FU, DTIC and Methyl CCNU, but these trials have alerted the urologic oncologic community to the need to pursue clinical research in the treatment of patients with prostatic carcinoma. In FY 1981, approximately $4.0 million of research in prostatic cancer was supported through contracts and grants in addition to the approximately $4.0 million supported through the organ site program.

Question 20.

When my staff and advisors review the literature on colon-rectum cancer we see there will be an estimated 138,000 new cases in 1982. And in checking the reports from the Large Bowel Task Force funded by NCI, we see that almost all of the ideas about cancer of the digestive tract are under urgent study within that task force, including the apparently important matters of speed of food movement through the tract, roughage, various metamorphoses, such as the body's creation of nitroso-amines, all apparently on the frontiers of this kind of research. Isn't this good?

Answer

The National Large Bowel Cancer Project was implemented in 1972 at M.D. Anderson Hospital and Tumor Institute where its Headquarters staff and chartered committee of scientists have successfully stimulated multi-disciplinary research in a heretofore relatively neglected area. This Organ Site Project currently accounts for about one-third of the total large bowel effort of the National Cancer Institute, with approximately $10.0 million of research supported through contracts and grants in FY 1981.

Question 21.

Each of these task forces serves as center of communication among those cancer scientists specializing in each of these fields. Isn't this useful?

Answer

Effective communication among scientists is a goal we strive for in all of our programs. The communication function among the multiple disciplines involved in the organ site projects is indeed useful and a good example of where our goal has been achieved. It is especially important to nurture and foster communications between the basic scientists and the practicing clinicians for it is through this symbiotic relationship that we can expect to achieve a more rapid application of useful basic research on the one hand, and the transmission of clinical needs and important anecdotal observations to the basic scientists for experimental solution on the other. In restructuring these programs this important function would certainly be retained. In fact, it is entirely possible that with the elimination of extraneous and redundant functions that communication will be enhanced.

Question 22.

Every NCI Director up to now has pleaded with the Congress to work against the personnel ceilings imposed by OMB. We know that the budget has grown much more rapidly than the NCI work force. Isn't it good that organ site task forces take some of the application review load off the backs of NCI and Division of Research Grant staffs?

Answer

The Organ Site Program currently has special decentralized mechanisms for program evaluation and planning, and for grant application review. These mechanisms even though they were extremely costly were justified at the time of initiation in 1972 because the tasks to be accomplished could not adequately be handled by expertise existing in the National Cancer Institute. There have been, however, some arguments which express the concern that the review by the working cadre consisting of members of the Organ Site Program may not be as rigorous as the review performed by the traditional study sections. The Organ Site Program continues at present to function with a relatively large external staff and with few NCI personnel, but the acceptability of this arrangement depends on how well this mechanism provides for the current tasks to be accomplished.

Question 23.

Dr. DeVita, since the board appointed a committee to look into organ sites and since that committee has reported to the board, and since the board clearly stated that it would consider the matter at its next meeting, isn't it rather contempuous of the board's authority to begin disbanding the organ site program before the board fully discusses its own committee's positive recommendations?

Answer

The Organ Site Program has not been disbanded nor changed from its current mode of operation. The National Cancer Advisory Board and NCI staff will discuss the program and possible changes at the May 1982 meeting. The program continues in its current mode until that time.

Question 24.

Dr. DeVita, you have designed two staff executive retreats to work on the budget every year. After the staff has gone over the matter completely twice, then you present it to the board. Wouldn't it be better if the board were represented at those retreats?

Answer

The retreats you refer to relate to periodic meetings of the Executive Committee and appropriate support staff which are intense working sessions covering 2 to 3 days. The purpose of these meetings are to discuss Institute programs or policies for presentation to the National Cancer Advisory Board and the Boards of Scientific Counselors. They cover a wide variety of subjects ranging from budget policy to program development to administrative management practices. These meetings are held specifically to prepare for Board meetings which thus enables Board members to receive the best thoughts and ideas of staff in an organized way. The Board is then able to review and comment on these program plans and recommend changes and additions as necessary. We believe this is a good division of labor which allows the staff to collectively reach decisions, saves the time of Board members and properly places these plans and policies before the Board for their advice and comment after all staff work is completed.

Question 25.

At what point in the fiscal year do you give the board the benefit of the staff's advice on budget?

Answer

The National Cancer Advisory Board meets four times per year and information regarding program plans and policies is provided at all these meetings. However, the most comprehensive meeting is the November board at which a presentation is made by the Division Directors and the Chairman of the Board of Scientific Counselors to review prior year program activities and future program plans.

Senator HAWKINS. Senator Hatch has notified me he is not coming back, so we will adjcurn the hearing at this time. Thank you so much.

Dr. BRANDT. Thank you very much.

Senator HAWKINS. The hearing in now adjourned.

[Whereupon, at 1:20 p.m., the committee recessed, to reconvene at the call of the Chair.]

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